CENTER FOR GLOBAL HEALTH R&D POLICY ASSESSMENT

R&D Tax Credits

A Tool to Advance Global Health Technologies?

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RESULTS FOR DEVELOPMENT INSTITUTE

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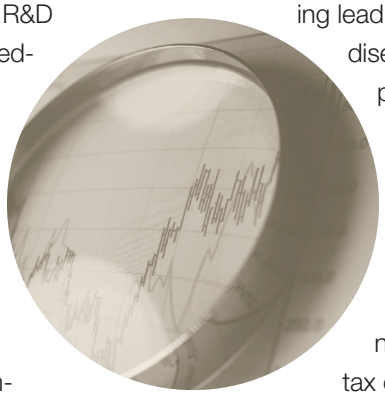
Acronyms

AMC	advance market commitment
CSR	corporate social responsibility
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HMRC	Her Majesty Revenue & Customs
IP	intellectual property
OECD	Organisation for Economic Co-operation and Development
PDP	product development partnership
R&D	research and development
R&E	research and experimentation
SME	small to medium enterprise
UNICEF	United Nations' Children Fund
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

Tax credits and other fiscal incentives are used throughout the world to encourage research and development (R&D) in the private sector. Governments use tax credits both as a tool to support broad R&D and as a targeted public policy to foster innovation in specific fields such as agriculture, energy, and medicine. Within the pharmaceutical industry, tax credits have been employed to increase research for orphan drugs, vaccines, and other high-priority public health products. By bringing down the cost of R&D through a reduction in tax liability, tax credits increase the return on investment of any successful products that result from the R&D.



Although tax credits have been successful in de-risking R&D by subsidizing costs and thus making products profitable for companies, the ability of a tax credit to encourage companies to conduct R&D for infectious diseases with weak and uncertain markets is less clear. This paper examines a specific tax proposal put forward by the biotechnology company ("biotech") Genzyme with the sponsorship of Representative Donald Payne and others, exploring whether and under what circumstances such a credit could be an effective incentive for the development of new technologies (drugs, vaccines, and diagnostics) for a set of "neglected" diseases of the developing world, which includes a mix of diseases with small to no markets.*

HR 3156 has proposed a 50% credit on nonclinical expenses for neglected-diseases research. After describing the design of HR 3156 and estimating its costs, this report examines some of its salient strengths and weaknesses, drawing lessons from relevant experiences with other ongoing R&D tax credits. The report assesses the proposed legislation along two criteria—whether a tax credit could successfully increase spending by firms on neglected-disease R&D (i.e., would the level of R&D investment grow because of the credit?) and whether such expanded spending could enhance the chances of developing a product with significant public health impact (i.e., would the higher level of R&D spending lead to better tools to fight neglected diseases, and would such tools reach patients sooner, as compared to what would happen without the credit?).

The analysis relies mainly on the existing literature and a small number of consultations with policy experts and is, thus, a first, preliminary examination of such tax credits. If tax credits for neglected-disease R&D are to be further investigated, more interviews with scientists and companies will be required.

Proponents of HR 3156 assert that it will incentivize a group of companies motivated to pursue neglected-disease R&D as an act of goodwill to fulfill the philanthropic and scientific interests of its staff and generate positive public relations. They thus view the credit as reducing or eliminating financial losses to the companies carrying out the R&D (i.e., to achieve a "no-profit, no-loss" objective) and not as a measure to make the neglected-disease products profitable.[1]

Our findings are largely consistent with this view, namely, that this proposed credit, *as currently designed,* will likely only interest the small number of established firms that are already conducting neglected-disease R&D for philanthropic reasons and

*These diseases include ascariasis, Buruli ulcer, Chagas disease, dengue fever, dracunculiasis, hookworm, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis, trachoma, trichuriasis, and tuberculosis. HIV/AIDS is sometimes included with these neglected diseases, even though it has a significant potential market in wealthier countries, a point that is also sometimes alleged concerning Chagas, dengue, and tuberculosis. For nearly all of these diseases, information on demand for drugs, vaccines, and diagnostic tests and for ability and willingness to pay for these new products is seriously lacking.

have revenues to offset against the credit. Since start-up biotech companies without revenue-generating commercial products cannot make use of the proposed credit, the measure is unlikely to bring many new innovator firms to the table. Furthermore, for the established firms with philanthropic motivations that are already performing neglected-disease R&D, it is unclear whether the proposed credit would induce them to increase their level of effort and investment or would simply subsidize spending that would have occurred anyway. Without provisions for more generous expenditure eligibility and for refundability that could improve the credit's appeal to firms, the credit on its own is unlikely to have broad uptake, either in expanding the number of companies involved in this kind of R&D or in persuading those who are already doing neglected-disease R&D to deepen their efforts.

One outstanding question is whether HR 3156 might change the profit equation for firms pursuing a drug against the subset of neglected diseases that may have a significant paying market in middle- and high-income countries, such as Chagas disease, dengue, malaria, and tuberculosis. In other words, might the credit turn what would otherwise have been an unprofitable R&D investment into a profitable venture? While it is difficult to make a definitive judgment on this, the experience in the United Kingdom with a similar tax credit for HIV/AIDS, malaria, and tuberculosis drug and vaccine R&D suggests that tax breaks alone are unlikely to persuade companies to shift their focus toward products to fight these diseases.

In summary then, the proposed credit may not have much positive impact on philanthropically inclined firms making no-profit, no-loss investments in neglected-disease R&D and, on its own, will probably not persuade companies to make an affirmative choice to develop a drug with profit potential, say against Chagas disease or tuberculosis, where there may be a relatively larger paying market with greater purchasing power.

If a tax credit is to have a positive impact for neglected-disease R&D, our assessment suggests that it would have to be redesigned in several ways, including (a) broadening the credit's eligibility to include clinical as well as nonclinical expenditures; (b) making the credit refundable for companies that do not have offsetting revenues; and (c) modifying the intellectual property (IP) and licensing stipulations so that companies can retain their IP for the more affluent markets, while ensuring access at affordable prices in lower-income markets. The level of the credit might also need to be raised above the 50% level proposed in this bill.

In addition, experience with biomedical incentive packages, such as the Orphan Drug laws in the United States, indicates that to achieve its goals, a neglected-diseases tax credit might have to be bundled with other measures such as government R&D grants to firms and certain forms of market commitments (price and/or volume guarantees). Without such measures, a tax credit alone seems unlikely to have sufficient strength to change significantly the R&D investment decisions of most firms.

To improve our estimation of the potential value of a neglected-disease tax credit and the ways in which such a credit could have a positive public health impact, we suggest that several kinds of additional analysis should be carried out. These might include surveys of small, medium, and large biopharmaceutical firms to ascertain the scope of their interest in conducting no-profit, no-loss R&D for products with weak and limited markets. In addition, new or improved demand forecasts for neglected-disease products, including those with a substantial or at least marginally profitable outlook (for example, a Chagas drug, dengue vaccine, or tuberculosis drug), are needed in order to judge better whether incentives such as a tax credit could make the critical difference in inducing firms to invest in R&D areas that would otherwise remain neglected by most scientists and product development organizations.

Introduction

The global health policy community has recognized the need for more R&D targeted at pressing global health priorities such as neglected diseases and other major infectious diseases. Despite the immense global burden of these diseases, they receive only a small amount of R&D funding, leading to an imbalance between global health needs and the products developed for health. For example, research for trachoma comprises only 0.1% of global R&D investment, or about $2.1 million, but the infection is endemic in 56 countries and affects 40 million people worldwide.[2,3] Infectious diseases are not only neglected in terms of research but they also disproportionately affect the world's poor, perpetuating the cycle of ill health and poverty.

To address the research gap, policy makers have proposed a menu of push and pull mechanisms, including advance market commitments (AMCs), prizes, novel grant programs, joint IP arrangements, and many other policies,* to accelerate research in high-impact global health areas. "Push" mechanisms like grants or other up-front payments reduce R&D costs, whereas "pull" mechanisms present a reward or incentive for completing a stage of product development. One such push policy, put forward by the biotechnology company Genzyme with the sponsorship of Representative Donald Payne and others, seeks to lower costs for American companies engaged in neglected-disease R&D by providing a tax credit for neglected-disease research.†

A tax credit falls within a broader family of fiscal incentives to encourage R&D. Specifically, the mechanism can directly reduce a company's tax liability. Governments around the world have used fiscal tools both to support broad R&D to foster economic competitiveness and as a public policy instrument to support high-priority research areas such as agriculture, alternative energy, and medicine. Within the health sector, there is some experience with using credits to make certain kinds of pharmaceutical R&D more profitable for companies, like drugs for orphan diseases and vaccines. There is much existing literature that examines the impact of tax credits in spurring broad R&D for products with recognized markets, but there is little information available about whether a tax credit is a useful measure to encourage more R&D for the set of neglected diseases, which includes a mix of diseases with small to no markets.

This report uses the tax credit proposal HR 3156 in order to assess the value of a neglected-disease R&D tax credit more broadly. After describing the design and estimated costs of the credit, its strengths and weaknesses are examined, drawing lessons from ongoing R&D tax credits. Based on this analysis, the report goes on to discuss whether a tax credit could result in more neglected-disease R&D expenditure from existing or new players and whether such expanded spending could enhance the chances of developing a product with significant public health impact in low-income countries. The analysis relies heavily on existing literature and a small number of consultations with policy experts. It uncovers some of the potential benefits and disadvantages of a tax credit for neglected-disease R&D, but further analysis is required to better understand the uptake of current fiscal measures.

*Many of these policies are the topics of other work undertaken by the Center for Global Health R&D Policy Assessment. See: http://www.healthresearchpolicy.org.

†The Genzyme Corporation, founded in 1981, is a biotechnology company that specializes in rare inherited disorders and has worked to advance global health technologies through its Humanitarian Assistance for Neglected Diseases initiative. Sanofi-aventis recently acquired the company.

Table 1: Comparative Studies of the Effect of Fiscal Incentives on R&D Investment[4,5]

Study	Estimated Elasticity of R&D Investment Resulting from Fiscal Incentives	Period of Analysis	Country
Australian Bureau of Industry Economics (1993)	–1.0	1984–94	Australia
McFetridge and Warda (1983)	–0.6	1962–82	Canada
Mansfield and Switzer (1985)	–0.04 to –0.18	1980–83	Canada
Bernstein (1986)	–0.13	1981–88	Canada
Berinstein (1998)	–0.14 (short run), –0.03 (long run)	1964–92	Canada
Berger (1983)	–1.0 to –1.5	1981–88	United States
Bailand and Lawrence (1987, 1992)	–0.75	1981–89	United States
Hall (1993)	–1.0 to –1.5	1981–91	United States
McCutchen (1993)	–0.28	1982–85	United States
Hines (1993)	–1.2 to –1.6	1984–89	United States
Nadiri and Mamuneas (1996)	–0.95 to –1.0	1956–88	United States
Bloom, Griffith, and Van Reenen (1999)	–0.16 (short run), –1.1 (long run)	1979–94	Australia and G-7

Note: The elasticities shown are negative to indicate a decline in government tax revenue. The higher the absolute value of the elasticity, the more investment per dollar of tax credit (e.g., the Berger and Hines studies show higher impact than the McCutchen or Mansfield and Switzer studies).

A Framework for Evaluating Fiscal Incentives for R&D and the Benefits of a Tax Credit

Strict definitions of R&D vary, but they tend to refer to novel work systematically undertaken in order to increase the stock of knowledge to generate new applications and devices.[6] HR 3156 has a number of design features that are based on existing tax credits for R&D that are not limited to global health alone. This section offers a brief overview of fiscal incentives for R&D and the strengths and limitations of R&D tax credits, since many of these strengths and weaknesses remain valid for a more narrowly targeted tax credit such as HR 3156.

Fiscal Incentives to Stimulate R&D

R&D is subject to the classic market failure that the private returns to investment do not always equal the social benefits. For example, basic R&D conducted by one firm may also lead to better technology in another field, but the full benefits may not be captured by the firm funding the R&D. If left to pure market forces, R&D would likely occur at a suboptimal level.[7]

To counter this, countries pursue a number of fiscal incentives such as tax exemptions, tax deductions, tax credits, and depreciation allowances* to foster the development of technology that can spur economic growth, lead to improved quality of life, and increase countries' competitiveness in the global market.[8,9] This also allows them to capture positive spillover

*A fiscal incentive is a tax measure that encourages a taxpayer to modify behavior in a specific way in order to receive a reduction in tax liability. See Appendix 1 for a list of key terms and definitions.

Figure 1: Advantages and Disadvantages of Tax Credits

Advantages	Disadvantages
Familiar to firms and governments—easy to implement	Tax credit does not perfectly align firm incentives with welfare maximization—firms may still pursue profit maximization over social welfare–maximizing products
Have the potential to leverage private investment	Depending on the design, may subsidize work that would have happened anyway
Unlike other more-directed "push" mechanisms, new innovators may respond to the incentive	Government unable to fully predict costs unless cap is placed on program
Firms are automatically eligible (no prequalification/application process)	
Give firms freedom to innovate in areas of technical strength or interest	

Other Considerations

Targeting: Tax credits tend to appeal to large firms with taxable income that have the resources to manage fiscal planning and absorb the time delay in receiving savings

effects for the public by intervening in the market, thereby increasing private R&D returns. An additional strategy is to directly fund R&D, which does occur in the United States and other countries. Tax credits offer another straightforward way to subsidize R&D without administering a direct grant or narrowly defining how companies should innovate.

One of the major questions when evaluating the effectiveness of a tax credit is to understand whether the credit stimulates new R&D. In some cases, tax credits may fund new work. In other cases, a credit may merely subsidize work that would have happened anyway.

Table 1 summarizes studies that look at the impact of fiscal incentives across sectors and highlights studies that found a significant investment response from firms. The studies underscore that the record of fiscal incentives in spurring *additional* R&D for every tax dollar the government forgoes is mixed. In some cases, tax credits successfully leverage private investment, making public dollars go farther. In other cases, R&D would have happened anyway—even without a tax credit. However, all of the long-term studies conducted of U.S. fiscal incentives show that firms increase R&D spending by at least $0.75 for every dollar of tax relief the government provides.

One advantage of tax credits compared to other innovative global health programs is that they are familiar and easy to implement. Governments know how to manage tax credits, and firms know how to use them. Like any other tax credit, a tax credit designed to stimulate innovations for neglected diseases has many of the potential advantages and disadvantages of general tax credits (see summary in Figure 1).

An additional consideration for broad tax credits is whether they actually maximize social returns. Because firms have a greater incentive to perform the R&D that generates the highest private return not the highest social return, public money will not necessarily flow to the projects that were originally intended unless the credit is designed carefully.[10] By comparison, direct grant programs and outcome-based incentives such as prizes allow the funder more control over the products that are subsidized. These mechanisms may be more effective alternatives in cases where a specific product profile is easy

Figure 2: Stages of Pharmaceutical R&D

to define up front (in the case of prizes) or a particular organization is known to be able to carry out the work (in the case of grants).[11]

If governments are not able to specify desirable products in advance or identify new innovators or if they simply want firms to retain capabilities in a specific area, then tax credits may pose an advantage. Tax credits may solve some of the selection and identification problems facing grant makers, who are inherently limited in knowing the future and potential capabilities of companies that are not currently working in the space.

A final consideration is that tax credits also tend to appeal to certain types of firms, specifically, large firms that have taxable income (unless the tax credit is refundable) and who have the resources to manage fiscal planning and can afford to finance the up-front cost of investment while waiting to receive the credit. An interviewee said that companies' senior financial management teams usually plan for fiscal measures after a consideration of the full range of measures that they qualify for; adjusting the selected portfolio for a new provision requires the time for additional financial analysis and decision making. Small firms, including start-up biotech companies without revenue-generating commercial products, may lack the resources to make these decisions quickly, resulting in less interest in tax credits. In the United States, 549 firms with revenue over $1 billion claimed over half of the $6 billion broad R&D net credit in 2005.[12] In a survey of about 200 small firms, roughly one-third responded as having filed for the U.S. R&D tax credit.[13] Appendices 2 and 3 list fiscal incentives available in other countries.

HR 3156

Description

The neglected-diseases credit, HR 3156, which was referred to the House Ways and Means Committee in 2009, falls within the broad family of fiscal incentives but narrowly targets neglected-disease R&D. Table 2 provides an overview of ongoing credits that address pharmaceutical R&D, and Appendix 4 reviews other tax credits that have been proposed for neglected-disease R&D. The bill would allow companies to claim a 50% credit for their nonclinical expenses for research on neglected-disease treatments.[14*] The notable exception from HR 3156 is research for HIV/AIDS, which does not qualify.

Nonclinical research expenses (those that appear to the left of Clinical Development in Figure 2) include those expenses incurred during preclinical development, where new compounds are discovered.[15] Companies could not use the credit for expenses incurred from clinical trials or regulatory review and could only apply for the credit if they have donated a royalty-free license to a foreign government or nonprofit research organization for the claimed research in that same taxable year. The proposed credit would piggyback on the rules of the United States' Research and Experimentation (R&E) credit to determine what types of expenditures are creditable, including, for example, restrictions on

*The diseases that qualify as outlined by the bill include human African trypanosomiasis, dengue fever, leishmaniasis, malaria, schistosomiasis, tuberculosis, Chagas disease, leprosy, lymphatic filariasis, onchocerciasis, Lassa fever, soil-transmitted helminthiasis, trachoma, yaws, dracunculiasis, cholera, Buruli ulcer, and "any other infectious disease for which there is no significant market in developed nations and disproportionately affects poor and marginalized populations as determined and designated by regulation by the Secretary of the Treasury in consultation with the Secretary of Health and Human Services."

Table 2: Ongoing Credits for Pharmaceutical R&D

	Orphan Drug Tax Credit	Qualifying Therapeutic Discovery Research Project Tax Credit	R&E Credit	Vaccine Research Relief Programme
Country	United States	United States	United States	United Kingdom
Purpose	Flat tax credit included in the Orphan Drug Legislation that provides a number of regulatory measures to expedite the approval of treatments for rare diseases.	Program aims to support work that helps meet an unmet medical need, brings down long-term U.S. healthcare costs, or advances a cure for cancer.	Incremental tax credit to boost R&D in the United States	Flat tax credit intended to increase research in drugs and vaccines for HIV/AIDS, tuberculosis, and malaria. It was expected to appeal to between 10 and 50 companies and increase R&D in the target areas by £20-50 million.[16]
R&D Stage	Clinical testing	All stages	Experimental/laboratory stage	All stages
Key Rules/ Features	50% credit for clinical testing for rare-disease treatments	Project-by-project application 50% tax credit (grant funding also available) Companies with less than 250 employees eligible $1 billion cap on program	The statute provides alternative mechanisms for computing the credit: **Regular credit:** A firm must establish a base level of expenditure (which must be at least 50% of current year expenditure) and generally may claim as a credit 20% of any qualified research expenses (specially defined) conducted over this level for the credit (see Figure 3). **Alternative Simplified Credit:** Firms can elect instead to claim a credit equal to 14% of the amount of their qualified research expenses (that exceed half of the average of such expenses over the prior three tax years.) Qualified research expenses include 65% of expenditures on contract research, which allows pharmaceutical companies to claim some of their costs for contracting projects to biotechs.[17]	40% credit for research on vaccines and drugs; credit for small to medium enterprises (SMEs) was reduced to 20% in April 2011 and will be unavailable to SMEs in 2012.[18] Cap of £7.5 million per R&D project claimed Enforces a minimum threshold of spending of £25,000 before companies can claim their expenses[19] Work subcontracted to firms in other countries eligible[20] Work subcontracted to domestic nonprofit or charitable research groups ineligible[21] Annual cost is less than £5 million; no information available on new projects that have emerged as a result of the credit[22]
Uptake/ Utilization	In 2006, total claims for the credit reached $159 million, continuing a mostly upward trend since the credit's inception.[23] Some suggest market exclusivity is more appealing to firms than the credit.[24]	IRS received 5,600 applications and provided awards to 3,000 companies.[25] Due to the high volume of applications, value of awards diluted to about $244,749 on average, resulting in less than 50% project cost recovery for most applicants.	In 2009, credit reached $5.6 billion in research claims. In 2006, $902 million of this flowed to the drug industry.[26,27]	Between 2003 and 2008, there were 10 claims made a year for this credit.[28]
Policy Lessons for Design of Global Health Credits	The legislation's mix of grant funding, market exclusivity, and a tax credit makes it difficult to discern which element is most effective in spurring additional R&D or if firms require all of the measures to change their R&D patterns. A similar comprehensive package might work for global health.	1) Interviews suggest biotechs are interested in the grant aspect of program; of the $1 billion disbursed, less than $19 million was provided as credits.[29] 2) The provision for refundability could be applied to the neglected-disease tax credit.	1) Base level of spending is controversial because companies must increase R&D each year to claim the credit and validate past years' expenditure. 2) Administrative and compliance burden is a barrier to uptake, particularly for small firms. 3) Lack of clarity over key statute definitions (i.e., qualifying expenses) raises transaction costs for all firms wishing to take advantage of the credit.	1) Firms have low uptake of program. 2) SMEs have particularly low uptake.[30] 3) The resulting cost of a global health tax credit is low.
Key Dates	Passed in 1983	Applicants awarded in November 2010	Originally introduced as part of Economic Tax Recovery Act of 1981; has been continuously renewed since then	Passed in 2003

the creditability of expenses incurred after the start of commercial production and expenses incurred to adapt existing drugs to new treatments.

The focus of this credit is to increase pharmaceutical company participation in early-stage work that can then be handed over to product development partnerships (PDPs) or other entities to take into late-stage development, following the so-called no-profit, no-loss model.[31] In designing this credit, its proponents are attempting to bring down the cost barrier for companies who are enthusiastic about supporting neglected-disease research projects and who would like to use some of their scientists' time toward this research but who are inhibited by the little to no prospects of recovering costs.

The credit is specifically aimed at large biotechs and pharmaceutical companies that have the necessary capital to conduct global health research without donor or grant support and have taxable income. There are many reasons why a company might pursue neglected-disease R&D. Although these efforts may not result in direct financial reward, companies may seek indirect benefits, such as improved relationships with developing-country governments, entry into emerging markets, and positive public relations. Neglected-disease research may also help unlock key scientific questions relevant to a company's other research or lead to a platform technology with applications in other commercial areas.

Proponents of the credit argue that the measure may help increase the overall funding allocated to neglected-disease research by offsetting the financial costs of low-profit or nonprofit work. Since a profitable pharmaceutical company faces a 35% corporate tax rate, a 50% tax credit would allow the company to recover 85% of its neglected-disease R&D costs if one assumes that each dollar spent on neglected-disease R&D would otherwise have been taxed as income and is now eligible for an additional credit.[32]

Smaller biotechnology companies might benefit from the proposed credit through partnerships with pharmaceutical companies, but the credit is largely designed to benefit existing players, namely, pharmaceutical firms and large biotechs. A pharmaceutical company could claim the credit for contracting out work to a biotech, but smaller companies with start-up losses would not benefit currently from the proposed credit, which is not refundable. In addition, the value of the credit might be limited for start-up companies that are structured as pass-through entities for tax purposes, such as partnerships. The amount of the credit that would flow through to the owners of such companies is limited by the alternative minimum tax.

Costs

Estimates from Policy Cures suggest that pharmaceutical companies and biotechs in the United States performed about $96 million worth of research for diseases largely prevalent in developing countries, or neglected-disease R&D, in 2008. The bulk of this expenditure, as outlined in Table 3, is divided between discovery/preclinical work and clinical development. The estimates below account for HIV/AIDS expenditure and products other than drugs, which are not covered by HR 3156, but given that the level of qualifying expenses is already low* and that HIV/AIDS poses significant morbidity and mortality around the world, cost considerations should include the full amount detailed below.

The provisions of HR 3156, which target nonclinical expenses, would allow a 50% claim on $50.9 million of this expenditure, suggesting a potential budgetary loss of about $25.5 million (assuming that all health products and HIV/AIDS are included). This is quite small given the total costs of other fiscal measures, but this figure is a rough estimate at best. The expenses displayed below have not been mapped against the qualifying criteria laid out in the tax credit bill and depend on the accuracy of firms' expenditure reporting to Policy Cures.

If such a credit was implemented and companies increased the amount of work that they do in this

* In comparison, in 2008 total R&D spending by pharmaceutical companies in the United States reached $65.2 billion.[33]

Table 3: U.S. Aggregate Pharmaceutical and Biotechnology Neglected-Disease R&D Expenditure

R&D Stage	FY 2008 (U.S.$)	FY 2008 (%)	Cost of 50% Tax Credit
Basic research	$710,804	0.70%	$355,402
Discovery and preclinical	$50,945,008	52.90%	$25,472,504
Clinical development	$32,428,157	33.70%	$16,214,078
Phase IV/Pharmacovigilance	$11,733,333	12.20%	$5,866,666
Operational research	$0	0.00%	$0
Unspecified	$487,211	0.50%	$243,605
R&D Total	$96,304,513	100.00%	$48,152,256

Updated: January 2010
Source: Policy Cures, G-FINDER, 2010

area, then the total costs would rise. Depending on the administrative burden of pursuing the credit and the total benefit to individual companies, not all companies would file for the measure. In this case, some of the work will continue without the subsidy, reducing the budgetary cost of the credit.

The credit would be most costly to taxpayers if it did not limit the stage of applicable research. If the credit subsidized all neglected-disease R&D, then the 2008 level of expenditure suggests that approximately $96 million worth of R&D expenditure would be eligible.

Another cost consideration is what public program "loses out" from the decrease in tax revenue. There is no straightforward way to calculate this trade-off and gauge if it is better to collect the tax revenue for other public initiatives. The greatest risk in terms of cost is that a tax credit might subsidize R&D that is already taking place and not result in additional research, resulting in a loss of tax revenue with no tangible benefit.

Strengths and Limitations in Design

The experience of other credits suggests that HR 3156 has some positive design features, but it lacks certain characteristics that would appeal to firms, which require further consideration. For firms, the greatest advantage is that the credit would be relatively easy to use. As designed, it is not administratively burdensome nor does it require establishing a base level of expenditure to prove incremental expenditure, as is the case for the R&E credit. Claims for the R&E credit represent 3% of total domestic R&D expenditures by the members of the Pharmaceutical Research and Manufacturers of America members, and only one in five pharmaceutical firms that filed income taxes in 2005 claimed the credit.[34] Interviewees confirmed the administrative difficulties associated with the R&E credit.

Despite its administrative ease, there are a number of design modifications that could broaden the appeal of HR 3156 for firms. These are discussed below:

Qualifying Expenditure. Opening up the credit to all stages of research could widen its utility to firms. Even if companies have a preference of handing off early-stage research to PDPs or other groups (since firms may lack the expertise or interest in late-stage product development for neglected diseases), there is no need to exclude the few firms who may be willing

Figure 3: Calculating a Qualifying Expenditure for the Regular R&E Credit[35]

Step 1. Establish a Fixed-Base Percentage

To establish a fixed-base percentage, firms must divide the sum of their qualified research expenses from 1984 to 1988 by their total revenue in that period. Special rules are provided for computing the fixed-base percentage for start-up companies, such as companies that had fewer than three tax years from 1984 to 1988 with both qualified research expenses and gross receipts.

Step 2. Calculate the Base Amount for the Tax Year

To establish the base amount for the current year, firms must average their revenue for the previous four years leading up to the filing year and multiply this average by the fixed-base percentage. This is the base amount.

Step 3. Calculate the Value of the Credit

To determine the amount of credit for which a company can file, firms must subtract the base amount from their current R&E expenditures or, if greater, 50% of their year's R&E expenditures. Firms generally can claim 20% of this value as a tax credit against their current-year tax liability, subject to certain limitations (e.g., the alternative minimum tax).

to see a product through to completion. The tax credit included in the Orphan Drug Legislation specifically aims to bring down the cost of clinical trials for orphan drugs, and in 2006, total claims for the credit reached $159 million, continuing a mostly upward trend since the credit's inception.[36] This stage of product development may be where companies need the most funding support.

HIV/AIDS research should also be included in the list of qualifying diseases as it poses significant public health challenges in low-income countries. The main disadvantage of including HIV/AIDS is that it already presents a large commercial market and ongoing research applies to both developed and developing countries. However, given the need for better and more inexpensive HIV/AIDS technologies worldwide, it should qualify for any potential global health tax credit.

Licensing. The requirement to donate a license to a nonprofit or foreign government is a prominent design feature of HR 3156. This stipulation is positive if the credit is intended to support work that is conducted out of goodwill—it ensures that the knowledge produced is available to the wider global health community. However, if the credit is intended to bring down the costs of pursuing global health products that have discernable markets, then the stipulation should be removed, so that firms can earn a fair return on their products.

Refundability. Like the R&E credit, HR 3156 is a nonrefundable credit, which prevents companies from receiving the dollar value of the credit if the credit exceeds their income taxes. This shuts out small firms (including start-up biotechs) with limited income. Allowing companies to receive a cash credit from the government rather than just decreasing their tax burden would allow companies with some but limited taxable income to use the credit to maintain cash flow. These smaller companies are unlikely to be interested in neglected-disease R&D for products with no market but may be willing to take on some risks for small-market diseases.

The Qualifying Therapeutic Discovery Research Project allowed biotechs to apply for credits or grants. One interviewee suggests that biotechs were most interested in the grant aspect of this program, as many emerging firms require cash in hand to pursue new research. And in fact, of the total $1 billion the program disbursed, less than $19 million was provided through tax credits; the majority of the funding flowed through the grant window.[37] If the neglected-disease credit were refundable and provided small firms with cash to further research, then it would capture participation from a wider range of innovators than just large companies.

Level of Credit. HR 3156 proposes a 50% credit, which effectively results in 85% coverage of firms'

Table 4: Design Features to Maximize Uptake for a Commercial Neglected-Disease R&D Tax Credit	
Level of Credit	>40% (exact level unknown)
Qualifying Stages of R&D	All
Qualifying Diseases	Diseases with modest markets (tuberculosis, Chagas, dengue, HIV/AIDS, etc.)
Refundability	Provision for refundability should be included
Intellectual Property	No restrictions

neglected-disease R&D costs. It is unclear if this level strikes the right balance between being high enough to interest firms and low enough to not overpay for the work. The existing R&E credit provides a maximum 20% credit on qualifying expenditures and the UK's Vaccine Research Relief Programme provides a 40% credit. Neither credit is being used to its full potential by pharmaceutical companies. Between 2003 and 2008, there have been only 10 claims made a year for the UK's credit, which is on the lower end of what policy makers expected since 10–50 firms were predicted to benefit from it. In the same years, over 6,000 claims were made per year for the UK's broader R&D credits.[38] Since the UK's credit focuses exclusively on the global health diseases that have larger product markets than the most-neglected diseases and still has low uptake, a higher credit level may be necessary to yield a reasonable return on investment for global health work.

Combining with Other Incentives. If a credit is being used to make a small market more commercially attractive, then industry's favorable response to the Orphan Drug Legislation suggests that a global health tax credit could be coupled with other incentives to widen the product market's appeal to firms. It is outside the scope of this analysis to determine what the right combination of measures for neglected-disease R&D should be.

There is an additional consideration that may increase uptake, but its advantages are less clear cut. Not including any geographic restrictions on qualifying R&D may make a credit more attractive to firms. Rather than using their U.S.-based scientists, it may be cheaper for firms to engage scientists in low- or middle-income countries in R&D. Consequently, a credit could allow expenditures that a U.S. firm incurs in another country to qualify for reimbursement. The disadvantage from a U.S. government perspective is that tax revenue is lost without necessarily supporting American innovation or global competitiveness. Since the UK's global health credit does not have a geographic restriction and still has minimal uptake, this aspect of the credit may not make or break firms' overall use of the credit, but it does have particular relevance for clinical trials conducted outside of the country.

Impact of a Neglected-Disease R&D Tax Credit

Based on the strengths and weaknesses of the design of the neglected-disease tax credit proposed by HR 3156 and the experience of other ongoing R&D credits, it is possible to look more broadly at whether a tax credit would be a successful addition to policy measures supporting neglected-disease R&D. For a tax credit to be valuable, it must be impactful on two fronts. First, it must successfully incentivize more firms to participate in neglected-disease R&D, or it must encourage firms already working in this area to increase the amount of resources allocated to their neglected-disease work. Second, the additional research undertaken should actually enhance the likelihood of developing a product with significant public health impact in developing

countries.

Will Firms Increase Their Neglected-Disease R&D Expenditure?

Although the actions of a firm will reflect the interests of its managers and staff, at the most basic level, a tax credit could appeal to two primary motivations within firms. A tax credit either could factor into a firm's regular financial planning by bringing down the cost of entering global health markets or it could make charitable neglected-disease work less costly and allow staff to conduct neglected-disease R&D for goodwill at little or no cost. A tax credit is more suited for the first purpose as it could appeal to a wider range of firms and might increase R&D spending. Firms who are interested in neglected diseases out of goodwill and willing to incur losses are more likely to be active in neglected-disease research already, and at most, might increase spending at the margin. These firms can also use existing broad R&D tax credits to subsidize some of this work.

R&D tax credits are by nature commercial tools that bring down the cost of conducting R&D and make product development more profitable for firms. A neglected-disease tax credit would be most successful if it followed this model. Interviewees noted that return-on-investment calculations are significant drivers of decisions to both conduct R&D and file for fiscal measures. A handful of the infectious diseases noted in HR 3156 have small or potentially profitable product markets. For this subset of diseases, a tax credit that sufficiently decreases the cost of R&D could render the modest demand for global health products into viable markets for firms.

If a tax credit is planned to stimulate R&D for diseases with small markets, then the provision to donate a license should not be included. Firms would have to retain the option to maintain the exclusive rights to their intellectual property to earn profits. To better understand the potential of tax credits for serving these smaller markets, more research would have to be done to clarify which products for global health have potentially profitable markets and to uncover whether firms have an interest in pursuing them.

Another commercial reason why firms may pursue this type of tax credit is for complementary benefits in more profitable research areas. In some cases, developing a technological platform or conducting research in one disease area can lead to product development in another. In these instances, a firm can use a neglected-disease tax credit as a means to support other work.

However, if firms are primarily motivated by goodwill or staff contentment (the no-profit, no-loss approach), then the market aspects of a tax credit are less relevant. From this perspective, a tax credit could benefit companies that have relationships with PDPs or other nonprofits that would be willing to devote more staff time to these partnerships if that time were subsidized. Scientists working in for-profit companies may be passionate about global health causes or interested in taking on new scientific challenges outside of their regular work. A tax credit may make pursuing these interests more financially feasible. Similarly, a tax credit for global health brings down the cost of engaging in a particular kind of corporate social responsibility (CSR). It is possible that companies would direct CSR funding from other nonprofit programs to neglected-disease R&D in order to enjoy the tax benefits. Allowing only incremental expenditure for diseases with no profit potential could help support these companies without paying for existing work, but increases in spending will likely be small.

Despite these possible motivations, the underwhelming response to the UK's Vaccine Research Relief Programme suggests that firms are unlikely to significantly increase global health expenditure through a tax credit alone.

Table 5 displays the HIV/AIDS, tuberculosis, and malaria R&D data reported to Policy Cures for the year 2008 in the United Kingdom. This amounts to about $42 million worth of R&D, but claims for the Vaccine Research Relief credit are usually less than £5 million a year, which translates to $9.3 million in 2008 U.S. dollars. The reporting requirements for this credit are bundled into the United Kingdom's popular broader R&D credits, which imposes a minimal administrative burden for pursuing the measure. This

Table 5: UK Aggregate Pharmaceutical and Biotechnology Neglected-Disease R&D Expenditure for HIV/AIDS, Tuberculosis, and Malaria

R&D Stage	FY 2008 (U.S.$)	FY 2008 (%)
Basic research	$0	0.00%
Discovery and preclinical	$37,337,117	89.14%
Clinical development	$4,081,970	9.75%
Phase IV/Pharmacovigilance	$46,668	1.11%
Operational research	$0	0.00%
Unspecified	$0	0.00%
R&D Total	$41,885,766	100.00%

Updated: January 2010
Source: Policy Cures, G-FINDER, 2010

credit also has few restrictions other than the disease areas. Most importantly, the Her Majesty Revenue & Customs (HMRC) finds that there are about 10 claims a year.* Since the number of claims have not been increasing, it is unlikely that the credit is attracting new firms to global health. Unless there is a reason that firms outside of the United Kingdom would behave differently, the low uptake of this credit indicates that a tax credit alone may not result in higher levels of neglected-disease R&D.

Some interviewees also suggest that companies locate their R&D close to sales points—for infectious diseases, this would mostly be in low- and middle-income countries. For example, a company interested in developing a Chagas product may conduct its research where Chagas is most prevalent. If this is accurate, then a tax credit in high-income countries may not influence R&D for health technologies relevant to low-income countries.

Will the Credit Enhance the Likelihood of Developing Products that Have Important Public Health Impact?

A neglected-disease tax credit may not have health impact immediately after implementation since the effects of tax credits are usually seen in the long term and since it offers the government only partial control over what type of R&D is being conducted. The scientific value of a broad neglected-disease credit is that it can help sustain the private sector's participation in global health by lowering the costs of participation. And since nearly all tax-paying firms would be eligible for a tax credit, it could attract firms who may be unknown to global health funding groups.

Pull mechanisms that have been implemented thus far attract firms for specific initiatives; for example, the AMC captured firm participation in R&D for a targeted pneumococcal conjugate vaccine. The AMC was a one-time incentive, however, and as such, cannot keep firms active in the global health space and encourage them to retain global health expertise. Tax credits have some potential to maintain firm involvement, but it is unclear if it is the best push mechanism to achieve this end. Push mechanisms that allow firms to determine their own areas of interest and partner with PDPs and nonprofits that they prefer may be better suited for this purpose.

Direct funding to companies' affiliated nonprofit research institutes or specific contracts could be as or more effective, with less uncertainty about whether

*Phil Armitage, e-mail message to author, September 15, 2010.

the program will be used or not. As with all R&D tax credits, there is no way of ensuring that companies take on R&D for the most socially productive projects, in this case, the most badly needed health technologies. Within the diseases eligible for HR 3156, companies face a greater incentive to perform R&D for the diseases with small markets. Direct funding gives policy makers greater control over the type of research being conducted and the freedom to allocate specific amounts of funding between disease areas.

Conclusions

This paper identifies some of the potential strengths and limitations of a neglected-disease R&D tax credit, focusing on HR 3156, and discusses more generally whether a tax credit could succeed in increasing the overall volume and quality of neglected-disease R&D, especially the development of novel drugs, vaccines, and diagnostics for the more than dozen neglected diseases that afflict billions of poor people around the world.

This analysis is based on a review of the literature and a small number of expert consultations and, thus, should be seen as a first look at the issue of fiscal incentives for neglected-disease R&D.

This assessment finds there are significant limitations to HR 3156 as currently designed. These limitations may reduce its effectiveness as a tool to increase R&D for the infectious diseases that are most prevalent in low- and middle- income countries.

1. The credit will likely have limited appeal and, thus, may result in low uptake by biotechnology firms. While the fiscal incentive proposed is relatively simple to understand and straightforward in its use, as a stand-alone measure it may be adopted by only a small number of larger firms that (a) are pursuing a charitable no-profit, no-loss strategy for neglected-disease technology development and (b) have revenue streams from other products against which they can offset the tax credit on their eligible nonclinical R&D activities.
2. Increases in neglected-disease R&D spending may be modest or minimal. Since HR 3156 will likely appeal mainly to the mid- and large-size firms who are already engaged in this area of R&D, they may only marginally increase their spending in response to the proposed credit. The new measure could also end up subsidizing ongoing work that would have happened anyway, without spurring many additional high-value projects.
3. The impact of such a credit on new products and the health outcomes of the poor are difficult to predict. Since tax credits allow firms to pursue areas of their own interest, it is hard to say which disease control efforts might benefit from a tax credit, though the legislation would restrict investments to a set of relatively neglected diseases. In addition, for many products, biotech innovators are likely to engage only in the earlier stages of R&D (lead optimization, preclinical development, and early-stage clinical trials), after which they will prefer to hand over their candidates to a PDP or a generic manufacturer who can produce inexpensively for a market supported financially mainly by external donor agencies. In that sense, even a successful tax credit would only move a new drug or vaccine part of the way along the path to a licensed product. Additional measures would be needed to “push” or “pull” the product all the way to manufacturing and distribution to patients.

One outstanding question is whether an R&D tax credit along the lines of HR 3156 might induce firms to develop drugs and vaccines for a subset of the neglected diseases that have stronger market prospects because they are widespread globally (e.g., malaria) and occur in either middle-income countries with strong purchasing power (e.g., Chagas disease in Latin America) or in low-income settings where donors are spending large sums of money on medicines (e.g., tuberculosis and HIV). While a tax credit could be a positive factor in firms’ decision to invest in R&D for products against these diseases, experience from the

UK tax credit for AIDS/tuberculosis/malaria drugs and vaccines and expert interviews suggest that the credit alone is unlikely to tip firms' calculus decisively in favor of R&D spending for these novel technologies.

To enhance the appeal and thus impact of HR 3156, at least for philanthropic no-profit, no-loss R&D, it may be worth considering several detailed modifications to the credit. These include widening eligibility to include clinical as well as preclinical expenditures, increasing the level of the credit, and permitting refundability for firms that do not have a stream of revenues.

Another possibility is to explore a redesigned tax credit not as a stand-alone policy innovation but as one component of a larger package of push and pull measures. Like the Orphan Drug Legislation, tax credits could be combined with other mechanisms, such as government grants, extended IP protection, and market guarantees (e.g., price and/or volume commitments, along the lines of the AMC for pneumococcal vaccines), to induce firms to invest in R&D for diseases like Chagas, dengue, malaria, and tuberculosis, which affect hundreds of millions of people and have substantial markets in middle-income countries in Latin America, Asia, and Africa.

Additional analysis could help to improve our assessment of the potential value of a neglected-disease tax credit and the ways in which such a credit could have a positive public health impact. For this paper, we only spoke with a limited number of biotech executives and a handful of experts on fiscal incentives for R&D. Beyond this, it would be useful to survey a larger sample of small, medium, and large biopharmaceutical firms to ascertain the scope of their interest in conducting no-profit, no-loss R&D for products with weak and limited markets and find out in greater detail how fiscal incentives would have to be designed and managed to make them sufficiently attractive to influence investment decisions.

In addition, new or improved demand forecasts for neglected-disease products, including those with substantial or at least marginally profitable outlook (e.g., a Chagas drug, dengue vaccine, or tuberculosis drug), would make it easier to judge whether incentives like an R&D tax credit might make the critical difference in generating a sufficient financial return, in order to induce firms to invest in R&D areas that would otherwise remain neglected by product development organizations. With such demand and price forecasts in hand, it would be possible to estimate the risk-adjusted returns to R&D projects for these "modest" markets and evaluate with greater precision how strong an impact such tax credits would have on firms' investment calculus.

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APPENDICES

1 Key Terms and Definitions

Alternative minimum tax: The alternative minimum tax is a U.S. income tax regime that requires taxpayers to compute their liability under a parallel set of rules that eliminate many tax preferences, with the intent of ensuring that all income earners pay some level of U.S. income tax.

Refundability: A credit is refundable if it is not limited by the amount of a taxpayer's tax liability and the difference is still provided by the government.

Depreciation allowance: A depreciation allowance is a tax deduction allowed to recover the cost of property or capital.

Tax credit: A tax credit is a dollar-for-dollar reduction in one's tax liability, whereas a deduction is a reduction in amount of income subject to taxation.

Tax deduction: A tax deduction is a reduction in a taxpayer's taxable income, resulting in a decrease in the gross amount from which a taxpayer's taxes are calculated.

Tax exemption: A tax exemption allows certain categories of taxpayer or certain categories of income not to be subject to current taxation.

R&D Tax Subsidies in Organisation for Economic Co-operation and Development (OECD) Countries

Table 6

Country	Rate of Tax Subsidy for $1 of R&D in 2008
France	0.42
Spain	0.35
Portugal	0.28
Czech Republic	0.27
Canada	0.25
Norway	0.22
Turkey	0.22
Korea	0.17
Hungary	0.16
Netherlands	0.16
Denmark	0.14
Japan	0.14
United Kingdom	0.14
Australia	0.12
Italy	0.12
Ireland	0.11
Austria	0.09
Belgium	0.09
United States	0.07
Poland	0.02
Greece	0.01
Finland	–0.01
Iceland	–0.01
Luxembourg	–0.01
Mexico	–0.01
Slovak Republic	–0.01
Sweden	–0.01
Switzerland	–0.01
Germany	–0.02
New Zealand	–0.02
OECD – Total	0.11

OECD 2010: Measures the generosity of tax incentives to invest in R&D, on the basis of the pretax income necessary to cover the initial cost of $1 of R&D spending and pay corporate taxes on $1 of profit (B-index). A value of zero on the chart would mean that the tax concession for R&D spending is just sufficient to offset the impact of the corporate tax rate.

3 Fiscal Incentives in Emerging Economies

Developing countries are beginning to use fiscal incentives to stimulate R&D. There is less experience with tax credits in emerging economies, but Brazil, China, Colombia, India, Malaysia, Singapore, and South Africa offer some type of fiscal incentive for R&D, including depreciation allowances, exemptions, and so-called super deductions that allow companies to claim over 100% of their R&D expenditure.[39,40] These measures attempt to increase the amount of foreign direct investment these countries receive and the overall volume of R&D occurring within the countries' borders. Table 7 highlights the super deductions available in a selection of emerging economies. Most of these deductions allow for materials, salary, and wage expenditures, and some subsidize capital expenditures.

Table 7: Super Deductions in Emerging Economies[41,42]

Country	R&D Super Deduction
Brazil	160-180%
China	150%
Colombia	125%
India	150%
Malaysia	200%
Singapore	130-200%
South Africa	150%

4 Previously Proposed Credits for Neglected-Disease R&D

In addition to the tax credits that have been implemented to stimulate R&D, there are at least two proposals for previous global health tax credits that did not successfully pass in the United States. These include the Project Bioshield II Act and the Vaccines for the New Millennium Act. The experiences of both suggest that passing a new fiscal measure for health R&D in the United States requires significant political will.

Project Bioshield II Act

This legislation was proposed to accelerate R&D for countermeasures to potential bioterrorism threats. It was posed as a follow on to the Bioshield Act that President Bush signed into law in 2004. The original act authorized funding for the U.S. government to purchase vaccines in the event of a terrorist attack. The new bill included a number of provisions to increase research for relevant vaccines, diagnostics, and therapeutics, such as advanced purchase funds, wild-card patents, and grants, in addition to two fiscal incentives.[43] The first allowed the creation of a new type of stock that would permit investors to avoid capital-gains tax on their countermeasure R&D investments, and the second created a 35% tax credit for countermeasure research. Despite creating a targeted credit, expenses for countermeasure research could still be used to establish baseline R&D expenditure for the R&E credit, but the work could not be claimed for both subsidies.[44]

At one point in the evolution of the draft legislation, with the endorsement of the International AIDS Vaccine Initiative, language was included that expanded the scope of the incentives to accommodate neglected-disease R&D. This was ultimately removed from the final legislation, along with the other R&D tax incentives. These incentives, particularly the wild-card patents, were seen as too much of a concession to industry. Wild-card patents would have allowed companies to extend patent life on non-countermeasure products, potentially raising the cost of blockbuster drugs.

The bill that was ultimately passed, renamed the Pandemic and All-Hazards Preparedness Act, provided the mandate for the Biomedical Advanced Research and Development Authority to oversee the use of countermeasures research funding. Although the target health areas vary, the original Project Bioshield II Act shares the same underlying purpose as the global health tax credit—to accelerate R&D in a high-priority health area with no private market. The obstacle that legislators faced in coupling an R&D tax credit with more aggressive incentive measures is a clear indication that any future tax credit, for global health or other R&D, cannot be viewed as being too generous to industry. However, the collaboration between the staff of Senator Lieberman's office, who sponsored the bill, and global health advocates suggests that there is some appetite for a neglected-disease R&D tax credit, despite the final outcomes of the Project Bioshield II Act.

Vaccines for the New Millennium Act

In 2000, Representative Nancy Pelosi, with the support of Senators John Kerry and William Frist, introduced the Vaccines for the New Millennium Act of 2000. This proposed legislation called for a tax credit that would incentivize private industry to develop vaccines for AIDS, tuberculosis, malaria, and other infectious diseases. The measure would allow companies to claim a dollar-for-dollar tax credit for vaccine

sales to groups like the United Nations' Children Fund (UNICEF) and the United States Agency for International Development (USAID).[45] The bill called for a total cap on claims of $1–1.25 million.[46] This tax credit is novel in that it offers a pull incentive by increasing the financial reward of global health product development and would cost nothing if the desired vaccines were never developed. This type of targeted credit allows the government to better set priorities for the type of product development that it wants to induce.

The bill went through the Senate Foreign Relations Committee and was introduced on the Senate floor. Although it is notable that the bill successfully survived an initial review, the Senate found that it had not flowed through the appropriate channels for tax legislation. The bill stalled at this phase. In the meantime, industry was not enthusiastic about an incentive that dictated what areas of research that they should pursue and did not advocate for the bill's passage. Senator Lugar reintroduced this bill as the Vaccines for the Future Act of 2007. The revised bill encouraged U.S. support for global health vaccine R&D, but it did not include the tax incentive of the previous iteration, perhaps to avoid the jurisdictional issues that had initially shelved the bill. The Vaccines for the Future Act also did not pass.

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