

Incentivising Research and Development on Vaccines Against the Most Deadly Infectious Diseases

Why a tax credit must apply to pre-clinical research

A vaccine for malaria, TB, or HIV/AIDS could save tens of millions of lives and generate expanded economic development in the developing world. But the private sector faces enormous economic and scientific disincentives to invest in research on these vaccines. A research and development (R&D) tax credit would help pharmaceutical and biotech vaccine companies dedicate more resources to research on desperately needed vaccines against the biggest infectious disease killers.

A critical component of an R&D tax credit is a credit on **pre-clinical research** – the early stage of research before human clinical trials. Because of the disincentives for research, there are now far too few vaccine products in the pre-clinical “pipeline”. And because most products fail, it is essential that multiple products for vaccines against each of these infectious diseases be undergoing intense research and development in private sector companies.

The development of innovative drugs or vaccines is dependent on trial and error. It is often unclear where the next great idea is going to come from, or what scientific theory is going to lead to the next great discovering. More often than not, taking results from a variety of experiments and theories makes advances possible. Thus, it is vital to broaden the pipeline to many new and innovative vaccine products.

Vaccine research must compete for corporate investment against other projects that will almost certainly have better risk profiles. Researchers within companies need the pre-clinical tax credit because the costs of pre-clinical research on the most challenging vaccines are particularly hard to justify given that the odds of success for any one approach are slim. Due to the unique nature of HIV, the ultimate approach for development of an effective vaccine is not obvious. Any mechanism that generates new areas of research is vital to increasing the number of promising new concepts into the research pipeline.

- **A tax credit on pre-clinical work would be comparatively low cost**

Several vaccine scientists estimate that pre-clinical development is approximately 5% - 20% of the total cost of developing a successful vaccine. Since the greatest development costs are at the clinical trials stage, the cost of adding a tax credit for pre-clinical work is quite modest compared to the credit on clinical costs. *An effective tax credit will provide incentives for both pre-clinical and clinical work.*

- **A tax credit on pre-clinical work is enforceable**

Pharmaceutical and biotech companies are known for their thorough record keeping. Pharmaceuticals must be able replicate, publish, and file documentation on every aspect of their research, so research labs keep exhaustive records of precise experiments and activities that would lend themselves to audit if necessary.

Businesses are also already required to keep records of similar nature for other tax related benefits such as ordinary business expenses, employment records, and depreciation of assets. Companies that have grants or contract from other organizations already keep such records.

According to NIH officials, defining and determining what research qualifies, as pre-clinical vaccine work would be a relatively straightforward activity.

It is generally very easy for someone familiar with biologics to identify the nature of experiments and development activities precisely for specific projects. This would especially be true if these fit in with a larger program effort. Claiming credits without proper documentation would be foolhardy, and would probably only occur with outright fraud. The purpose of research records would be obvious to another researcher.

- **Comprehensive Approaches are Required**

Accelerating drug and vaccine development requires tailored interventions at each step in the R&D and delivery processes, including subsidizing the costs of research through R&D tax credits and other incentives (“push” interventions), establishing viable markets (“pull”), and improving health care infrastructures.

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