

**CONTRIBUTION TO THE UNITED NATIONS SECRETARY-GENERAL'S HIGH LEVEL  
PANEL ON ACCESS TO MEDICINES**

**THE ROLE OF R&D SUBSIDIES FOR CLINICAL TRIALS IN PROGRESSIVE DELINKAGE  
OF R&D COSTS FROM PRODUCT PRICES**

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**February 28, 2016**

The grant of temporary monopolies is widely used as an incentive to induce investments in R&D for the development of new drugs, vaccines, diagnostic devices and other products. These monopolies are associated with high prices, access barriers and unequal access, as well as a number of other shortcomings, and are also ineffective at inducing investments in the advance of basic science, projects where the prospects of commercialization of low-end drugs for tropical neglected diseases, to mention a few well known areas of market failures.

In order to achieve greater and more equal access to medicines, prices have to be lower. Many groups are asking that policy makers delink R&D costs from product prices. We have examined various delinkage strategies in a series of papers [see: Additional references on KEI's work on delinkage]. Many policy makers are warming up to the notion of delinkage, but find the challenges of setting up radically new financing mechanisms a daunting challenge.

This submission highlights a particular set of policy options that can be used as part of a progressive implementation of delinkage. In short, we consider the expansion of subsidies for clinical trials tied to policies to reduce the costs of products, either directly through lower prices or by shortening the terms of exclusive rights, or some combination of the two options. The basic idea is that if governments collectively reduce the costs of R&D inputs, they can also reduce the size of incentives to induce investments in such R&D inputs.

This suggestion takes as its point of departure the U.S. Orphan Drug Tax Credit (ODTC) program. [2] The ODTC provides for a tax credit that directly reduces a company's tax liability by 50 percent of the qualifying costs of trials on "certain drugs for rare diseases or conditions." Since the creation of the tax credit in 1983, the credit has been available every year, except for 1995 through 1997. The statutes and regulations that set out the rules for the credit have changed over time, gradually expanding the number of products and trials that qualify for the credit, and liberalizing the carryforward provisions, which has been a benefit to smaller

companies with no current profits. The credit is an important subsidy for clinical trials, but only for for-profit entities that file income tax returns. The U.S. Internal Revenue Service publishes some data on the use of the credit, but nothing that can be attributed to a specific trial or company.

Over time, the Orphan Drug Tax Credit has become an under-recognized government subsidy for R&D. In 2015, the FDA approved a record 45 novel drugs. Of the 45, 21 qualified as Orphan Drugs (47 percent of all approvals), and were eligible for the tax credit. [1] For cancer drugs, the role of the ODTC is even more important. From 2014 to 2015, 80 percent of all new cancer drugs qualified as Orphan products.

There are several important aspects of the ODTC.

1. There is no transparency of the amount of the subsidy for specific drugs or specific trials.
2. The ODTC only subsidizes for-profit entities, and does not provide a benefit to universities or non-profit drug developers, like DNDi, engaged in drug development.
3. Non-US firms that sell products in the United States can and do claim the credits.
4. U.S. taxpayers pay for the ODTC. No foreign country pays for this R&D subsidy.

The proposal is this: A group of governments could agree, collectively, to expand the current 50 percent ODTC to a higher level of subsidy, say 75 percent, and extend the subsidy to a larger set of drugs and trials. For this to happen, the subsidy would be paid for by a larger set of governments, perhaps lowering the costs for the United States and having other countries share more of the costs of the subsidies.

Why would governments want to consider this? Because at the same time, the governments could either lower expected reimbursements or shorten the effective term of the monopoly, perhaps by eliminating some *sui generis* regulatory monopolies and patent extensions, or issuing compulsory licenses before the full term of the patent.

The combination of expanding subsidies on clinical trials and reducing prices (and profits) from the monopoly protects innovation and patients simultaneously, and it can eliminate the stigma and negative consequences of lowering drug prices on innovation.

## **Implementation**

The proposal provides a concrete method of progressively delinking R&D costs from drug prices, using well known and familiar policy interventions.

Policy makers should have more transparency of the use of the ODTC for specific drugs and trials.

Policy makers would have to consider and model the costs and impact of deeper and more widely available subsidies for R&D inputs, including in scenarios where prices are lower, or monopolies are shorter.

### **Impact on Policy Coherence**

The key to policy coherence is to protect both access and innovation. This proposal illustrates that this can be done using well known and familiar policy interventions.

### **Impact on Access**

The lower prices obtained through the intervention will expand and make access more fair.

## **SECTION 3: REFERENCE AND BIBLIOGRAPHY**

### **Please provide your references and bibliography \***

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