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Mr Andrew George, MP

The Rt Hon Nick Herbert, MP

Mr Virendra Sharma, MP

The House of Commons

LONDON SW1 0AA

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Dear Mr George, Mr Herbert and Mr Sharma

We are writing to thank you for your recent All Party Parliamentary Group report on research and development (R&D) for global health. The report raised awareness of issues which might otherwise have escaped the notice of members of both the House of Commons and the House of Lords. It is likely to excite considerable interest outside Parliament.

However, we feel that members without your own background in the subject and those outside Parliament may not realise that the report's focus on intellectual property (which, as you know, is chiefly relevant to commercial R&D) means that many of its recommendations are less relevant to neglected disease R&D, and may even be actively damaging if applied there. We unfortunately already have evidence that this is the case. The heavy focus on IP, as well as a failure to clearly distinguish between commercial and neglected disease R&D, has unfortunately resulted in the inappropriate importation of some analysis and recommendations from the commercial to the neglected disease areas, as discussed below.

Although our focus is chiefly on neglected diseases, we also note in passing that the implications of the report's IP focus on commercial development of medicines have not been fully explained. Many readers may therefore be unaware that several of the recommendations effectively also support a major change in *commercial* R&D policy, in particular a shift from a commercial pharmaceutical system to a publicly funded and managed pharmaceutical system (for example, Recommendation 2a). We realise this approach has strong support among advocacy groups, many of whom made submissions in its favour to the APPG, however we wondered if it was the Committee's intention to support this approach and, if so, why other approaches were not equally considered.

Lack of distinction between commercial and neglected diseases, and the roles of IP in each

There are significant differences between the problems posed, and solutions needed, for commercial and neglected diseases. The chief problem for the former is how to secure affordable access to proprietary commercial medicines; for the latter, it is how to structure and fund public and philanthropic R&D.

- Commercial diseases affect people in all income groups and are a burden for both rich and poor countries -- for example, cancer, cardiovascular disease, diabetes and adult HIV. These diseases have large paying markets which stimulate a great deal of pharmaceutical industry innovation. The issue for these diseases is that the final prices of medicines (protected by proprietary IPRs) can be too high for the poor. In response, there have been calls for an alternative R&D model controlled and funded by the public sector. The goal is not to stimulate R&D (which is plentiful), it is to move control of R&D from the private sector to the public domain in the hope that this might keep prices down. This would be achieved by removing profits and IP as the driver for innovation and replacing them with public funding (grants, prizes, open source, an R&D treaty etc.), as noted in the APPG report.
- Neglected diseases affect people only in the poorest countries -- for example malaria, Ebola, Guinea worm and sleeping sickness. Their key problem has little to do with private control of IP and R&D, since these diseases by definition fall entirely outside the commercial IP-driven R&D system. Instead, it revolves around the public and philanthropic responsibility (including industry philanthropy) to drive innovation in neglected diseases, and how this should best be funded and structured. For these diseases, there is no point in asking for an alternative model to IP-driven for-profit R&D: firstly, because there *is* no IP-driven for-profit R&D (by definition); secondly, because the public and philanthropic sectors are already using an alternative model and; thirdly, because this model already delivers the stated goal of creating new medicines at low-or-no profit prices for the poor. The G-FINDER reports notes that $3bn is invested into this alternative model each year; it has already created 44 new medicines for the poor since 2000; it now has over 350 product candidates in the pipeline and; R&D is already funded by the public and philanthropy and conducted using non-profit models, open source models and a range of voluntary agreements between public and private sector groups, in particular Product Development Partnerships (PDPs). This is well-documented.
- A subset of diseases is in a crossover group, for instance, dengue and TB. These have a small market in wealthier developing countries and some are re-emerging in high income countries. But there is also a large non-profit R&D sector because these diseases predominantly affect poor people who cannot afford to buy new medicines. For instance, although there is commercial R&D for TB, over three-quarters of all new TB drug and vaccine R&D is low-or-no profit R&D conducted by Product Development Partnerships (PDPs) such as the TB Alliance.

The inapplicability of many IP-based solutions to neglected disease R&D

The report's recommendations (based as they are on initiatives to target privately held IP) could put at risk the existing non-profit neglected disease R&D approaches. The neglected disease R&D pipelines described above rely heavily on philanthropic inputs of industry IP under non-profit agreements. This approach has been very successful to date in delivering vital new no-or-low profit medicines for neglected diseases of the poor, including the following – all developed by PDPs and industry on a non-profit basis:

- The first malaria medicine for children ever, priced at $0.38c per treatment
- A meningitis vaccine for $0.50c that has wiped out meningitis A in the African countries that have used in

- A new TB drug in final stages of development that will cut the cost of treating drug-resistant TB from $5000 per patient to $50-$90 per patient; and cut treatment time for patients from 2 years to 6 months
- A vaccine vial monitor that has saved $130m in wasted vaccines in the developing world in the past ten years alone.

The recommendations that companies be forced to provide their IP for open source use, or else lose their R&D tax breaks and/or the funding to their PDP partners (Recommendations 1d and 3b) are dangerous and, we believe, wrong.

Compulsory open-sourcing of IP as a condition of their involvement assumes that IPRs are the same problem for neglected diseases as they are for commercial diseases. They are not. Many companies routinely and voluntarily provide their IP to PDP partners for neglected disease use (why would they not, since this IP is valueless in commercial terms but highly valuable in global health and PR terms). Every PDP candidate in development with industry represents such a deal (there are hundreds of such projects); most companies routinely provide access to their private IP for screening for potential neglected disease compounds and; most PDP agreements with companies include low-or-no-profit pricing for the developing world on the final products. Developers of non-profit medicines have estimated that IPRs are an obstacle in less than 10% of projects, even in crossover commercial areas such as TB drug development. Again, these are well-documented facts.

Compulsory open-sourcing – as opposed to the non-profit voluntary agreements currently used - achieves little but runs a high risk of damaging this neglected disease model, built up over the past 15 years. Companies participate voluntarily in these philanthropic partnerships at a financial cost to themselves and with no expectation of profit: why would they now agree to deals with PDPs that require them to relinquish any control of their IP (including, in the case of screening, of potentially-commercial compounds in the same 'family')? The risk of encouraging or forcing companies to pull out, or deterring new companies from participating, is high; and to incur this risk to gain public control of IP (which is not even the problem) seems illogical.

Losing company participation in neglected disease R&D is not a gain, it is a loss. We note Novartis' recent voluntary handover to the TB Alliance of the global IP rights to Novartis' TB drug compounds (proof, if more were needed, of the very different role of IP in neglected diseases). While reported in some media as a victory for some public health advocacy groups, this is far from the case. Previously, Novartis funded and conducted in-house TB drug discovery at their philanthropic neglected disease Institute, advised by the TB Alliance, with a view to providing developing world access to any resulting drugs at low-or-no-profit prices. Now the TB Alliance holds the IP rights, but without the funding or industry expertise and assistance previously available from Novartis to develop these compounds. We have gained nothing and lost a great deal. It is vital that the APPG encourage the global health community to shift the focus back from IP (a red herring in these non-commercial areas) to the real problems of neglected disease R&D – how to secure public and philanthropic funding and pharmaceutical expertise.

As a final point, we believe the report's usefulness would benefit from greater nuance. There is a failure to distinguish between poor, low-middle and upper-middle income countries (except incidentally in a reference to a scheme run by WIPO). Brazil (with a per capita GDP of $15,000) has far more in common with Bulgaria (per capita GDP of $16,000) than with the Central African Republic (per capita GDP of $600). China is about to become the world's third biggest pharmaceutical market. These are stark examples but even India (per capita GDP of $5,500) is more similar to OECD countries than to the Central African Republic. Upper middle-income countries such as China, Brazil and Thailand have different and sometimes conflicting interests to low-income countries, including a

greater focus on commercial pharmaceuticals for non-communicable diseases (in other words, IP issues) rather than neglected disease R&D. In some cases they have a domestic pharmaceutical industry making NCD products in competition with multinational pharmaceutical IP-holders.

Secondly, R&D gaps cannot really be sensibly discussed at disease level. Diagnostics, drugs and vaccines have extremely different costs, risks and markets, meaning that a HIV diagnostic may be commercial, but a HIV vaccine may not. In the same way, TB diagnostics have a substantial market in the West, while TB drugs do not; and adult HIV drugs have a multi-billion dollar Western market while there is no market at all for paediatric HIV drugs. These distinctions are absolutely vital in determining whether an R&D area is commercial or neglected, and thus what the causal problem is and what solutions can best address it. The report's credibility and usefulness would benefit greatly from clarifying these distinctions, and ensuring they are reflected in the text and recommendations.

Given these concerns, we urge the Committee to direct the researchers working on this report to clarify, extend or re-write the relevant sections and recommendations, in particular to review several of the IP-based recommendations on neglected disease R&D. We would also ask the Committee to request that the researchers provide a stronger evidence base for their findings, which in some cases contradict the available empirical data and in other cases have the flavour of advocacy rather than of facts on which Her Majesty's Government can reliably base its decisions.

Yours faithfully

Mary Moran

Mark Chataway

Dr Mary Moran is a specialist in neglected disease R&D. She is Executive Director of Policy Cures, a non-profit organisation whose mission is neglected disease policy analysis. Dr Moran was a participant in two of the four WHO expert consultations on global health R&D over the past decade, including as a member of the third WHO Expert Working Group on R&D (the EWG). She is an adviser to the Health Impact Fund; an expert adviser to a range of organisations including the OECD and EDCTP; and has conducted analysis on R&D policy for the WHO, World Bank, GAVI, AusAID (now DFAT), Bill & Melinda Gates Foundation and Wellcome Trust, among others.

Mark Chataway is a consultant based in Wales who works on global health issues for a range of not-for-profit, government and commercial entities (none of which have been consulted about the contents of this letter). Last year, he moderated a PATH workshop on ways to promote innovation throughout the steps of clinical research. He also moderated an international think tank on maintaining innovation in vaccine development convened by a group of academics from France, the UK and the USA. He served on a South African Ministry of Science and Technology panel on HIV vaccines and helped establish the international programmes of the International AIDS Vaccine Initiative. None of the organisations mentioned has had a chance to read or comment on the ideas in this letter.