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Standing Committee on Industry, Science and Technology
c/o Clerk of the Committee
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6

Dear Committee Members:

Re: CAMR Reform

Please accept this brief submission to the House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-393.

I am a Professor of Economics at the University of Calgary and an expert on pharmaceutical markets. A brief summary of my expertise in this area: I hold a PhD in Economics, focusing on Industrial Organization, from the University of Toronto; I have published extensively on competition and innovation in pharmaceutical markets as the focal area of my research; I have consulted for companies, governments, and industry associations regarding pharmaceutical matters; I have served as a committee member for the Patented Medicine Prices Review Board (PMPRB); and I have appeared as an expert witness in numerous cases at the Federal Court and the Federal Court of Appeal regarding pharmaceutical matters. In addition, I have an interest in matters relating to innovation and access to pharmaceuticals specifically in developing countries and have published several papers in this area.

I wish to comment on two issues. The first relates to *whether streamlining CAMR serves any purpose*, given that (a) there are other obstacles to effective treatment of patients in the poorest countries, (b) some drugs are currently available at low prices in some of those countries because of subsidies or company policies of offering concessionary pricing, and (c) many such countries do not have effective patent regimes or many important drugs are unpatented in those countries (because they are not seen as significant enough markets to warrant the patenting process or lack production capability).

The answer to this question is simply that if there is are instances in which there is demand for products under a streamlined CAMR, it must be because it serves a purpose. If other obstacles to the effective use of medicines (e.g. insufficient diagnostics, etc.) are too severe in a given developing country, then it seems unlikely that there will be a request to use CAMR; or if it is used, it will result in small quantities being supplied. For those situations where these

obstacles have been or are being overcome, CAMR can play a role in getting those medicines at reduced prices.

If a given drug is available to a developing country at low prices already, then it seems unlikely that a country would seek to purchase it from a Canadian generic manufacturer under CAMR, and in this case either there would be no request to use CAMR. Where the drug is not available at a suitably low price (e.g., because it is not available from a generic manufacturer, or there is insufficient competition because of only one or two generic manufacturers competing with the patentee), then again this may be a situation in which CAMR can make a difference by enabling competition.

Finally, even if some developing countries lack effective patent regimes or there is relatively little "patent coverage" on pharmaceutical products, this does not make a regime such as CAMR irrelevant. Countries lacking effective patent regimes most likely also lack effective pharmaceutical production capabilities. Therefore, they would be precisely the sorts of countries that need to import generics from other countries that do have this production capacity (including Canada), and it is because of this generic production capacity that these potential producer countries are likely to have patents covering the medicines needed. Therefore, to supply the needed imports to developing countries lacking their own production capacity, producer countries require a mechanism (such as CAMR) for overriding these patents to enable exports.

In essence, one way of seeing the value of CAMR is that if countries apply to use it, there must be some value. However, if countries are to apply to use CAMR, then it must be seen as useable. Under CAMR as it currently exists, the regulatory and administrative restrictions appear quite cumbersome and thus it seems unlikely to be used much, if at all. Streamlining CAMR to make it easier to use will only lead to application of the streamlined regime in cases where there is some value to its use. At worst, if even a streamlined CAMR goes unused because developing countries are able to source needed pharmaceuticals in other ways, then it is irrelevant. At best, a streamlined CAMR helps address at least some of the needs of some developing countries for medicines at more competitive prices.

The second issue is *whether streamlining CAMR as proposed by Bill C-393 would result in lowered incentives for innovation in the pharmaceutical sector in Canada*.

There is no reason to think that modifying CAMR as proposed by Bill C-393 would lead to a reduction in R&D spending in Canada. Pharmaceutical R&D is globalized and any product that would be subject to possible compulsory licensing for export under CAMR will be the result of R&D expenditures in many countries. Patentees will consider a range of factors in determining where and to what extent to invest in R&D, such as tax credits for research expenditures, the university infrastructure to support and collaborate in research, the environment for conducting clinical trials (e.g., regulatory requirements, availability and ease of recruitment of participants, etc.). Furthermore, the operation of CAMR to enable compulsory licensing of patented pharmaceuticals solely for the purpose of export to markets of limited economic significance to patentees will apply to eligible products patented in Canada regardless of where the R&D has taken place.

It is difficult to see how a streamlined CAMR would offer any economic rationale for originator pharmaceutical companies to reduce their spending on R&D in Canada. The only possible connection between reforming CAMR and decreased R&D spending would be that patent-holding pharmaceutical companies elect to punish Canada for changing CAMR by reducing R&D spending here – not for an economic rationale but for other reasons.

Streamlining CAMR could result in its becoming more useable. If it were then used, that would constitute evidence that it was and is needed. If it remains unused, that would indicate that other obstacles, or lower-cost production elsewhere, make it unnecessary. But if it remains unused, then there can also be no objection to its being changed. It would seem, therefore, that objections to reforms that would increase the likelihood of CAMR being used are fundamentally objections to the use of CAMR per se to encourage and enable possible competition in the markets of eligible importing countries that might seek to use the regime because of a need for less expensive medicines.

Finally, I remind the committee that *until 20 years ago Canada had a regime of compulsory licensing of pharmaceuticals, and that every member of your committee has benefited from low prices on pharmaceuticals during that time*. Countries like Rwanda do not have the scale or level of industrial development to support an active generic industry, and accordingly depend on other countries, such as Canada, to be able to effectively use their own TRIPS-compliant compulsory licensing provisions (or to rely on the absence of domestic patent applications). There is a risk of hypocrisy in claiming that while we benefited from the use of compulsory licenses, we expect very poor countries to do without them.

Sincerely,

Aidan Hollis
Professor of Economics