Cystic Fibrosis Canada Ontario
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Hon. Patty Hajdu
Minister of Health
Government of Canada

February 27, 2021

Dear Minister Hajdu,

We are members of an all-party caucus on emergency access to Trikafta, a game-changing therapy that can treat 90% of the cystic fibrosis population. We are writing to thank you for your commitment to fast-tracking access to Trikafta and to let you know that we are here to collaborate with you in this work.

We know that an application for review of Trikafta was received by Health Canada on December 4th, 2020 and was formally accepted for review on December 23rd.

We are also aware that the Canadian Agency for Drugs Technologies in Health (CADTH) body that evaluates the cost effectiveness of drugs is now reviewing Trikafta for age 12 plus for patients who have at least one F508del mutation. This indicates that Trikafta was granted an 'aligned review,' the fastest review route. The aligned review will streamline the review processes by the Patented Medicine Prices Review Board (PMPRB) to set the maximum amount for which the drug can be sold, and by Health Technology Assessment bodies (CADTH and INESSS) to undertake cost-effective analyses, which can delay the overall timeline to access to another 6 months or more.

An aligned review will reduce the timelines of all of these bodies to between 8-12 months or sooner. But that is just one half of the Canadian drug approval system. It then goes to our public plans for price negotiation and listing. We must also ensure Trikafta will be approved to treat all who need it.

As a caucus we are concerned that the drug may not be indicated for all of the mutations it treats and it should be. We are also discouraged to know that, once the drug leaves the review bodies mentioned above, there are no guarantees on how long it will take for medicines to get reimbursed to those who need them. This is because there are no set timelines for price negotiations between the pan-Canadian Pharmaceutical Alliance (pCPA) and manufacturers to achieve list prices for drugs on our public plans.

We appreciate that you have committed to working with your provincial colleagues to expedite access to Trikafta. Right now, the pCPA is negotiating two other modulators – Kalydeco and Orkambi – which provides an excellent opportunity to include Trikafta in these negotiations to expedite access.

To help us determine how best to support this important work, can you please clarify the following:

- Are you working with Health Canada to ensure that the broadest indication possible will be granted, as was done in the U.K. and, recently, the U.S., which will include all indicated mutations?
- How are you working with provinces regarding access to Trikafta and other disease modifiers through the pCPA?

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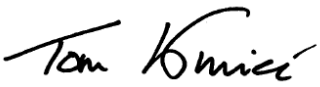
- What can we do to help?

Minister Hajdu, we appreciate your leadership on this file and look forward to helping advance access to Trikafta wherever we can.

Sincerely,



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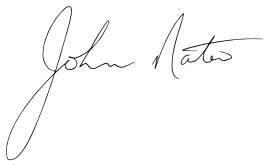

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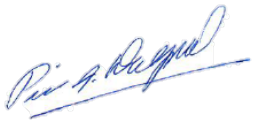

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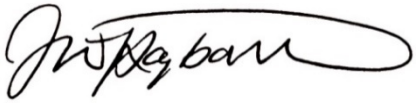

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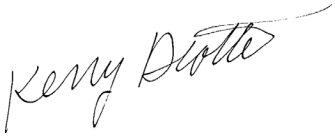

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