



Rt Hon Theresa May MP  
10 Downing Street  
London  
SW1A 2AA

Rt Hon Matthew Hancock MP  
Department of Health & Social Care  
39 Victoria Street  
London  
SW1H 0EU

31st January 2019

Dear Prime Minister & Secretary of State,

We write to you as health campaigners and parents of young children with cystic fibrosis who could be treated with Vertex Pharmaceuticals' drug, Orkambi (lumacaftor-ivacaftor), asking that you let our children breathe by pursuing Plan B on Orkambi - a Crown use licence that would allow the NHS to procure an affordable, generic version of the drug.

We cannot explain, let alone expect you to understand, the sheer dread and helplessness it causes us to know that we are likely to outlive our children. The anguish in knowing that a drug exists that can change that - sparing them unnecessary suffering and decline in health - but that they are denied access, is unbearable. Orkambi, and the more recently licensed drug Symkevi, will change the outcomes for patients with cystic fibrosis from a condition that causes frequent and progressive illness leading to early death (over half won't reach their 32nd birthday) to a manageable condition with the potential for significant extra years of health and life.

To refuse our children, and thousands of others, the only drug that can alleviate the progression of their disease - a drug which perversely is made and sold to the world from the UK - is inhumane. Patients in 12 other European countries including Ireland and soon Scotland, are seeing their outcomes improve whilst our children continue to suffer and cystic fibrosis patients continue to die prematurely.

The NHS Long Term Plan states that 'we will be targeting investment in improved treatment and support for those with respiratory disease, with an ambition to transform our outcomes to equal, or better, our international counterparts'. Without action to break the Orkambi deadlock then the cystic fibrosis community will be excluded from this ambition.

Negotiations have completely failed, with NHS England stating that Vertex's pricing is 'unsupportable' and Vertex confirming they do not intend to re-engage with NICE. Plan A - securing a fair and affordable price from Vertex - has not worked.

As our Government we call on you to execute Plan B on Orkambi. Use the legal powers enshrined in the 1977 Patent Act to issue a Crown use license and allow the NHS to source a generic version so that our children and all patients can be treated.

The WTO's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and the Doha Declaration which clarifies the terms of the agreement, make it clear that there are legal safeguards to ensure public health is not sacrificed at the expense of the interests of the owners of intellectual property rights. The ability to issue Crown use licences is one such safeguard.

Up until the 1970s the NHS regularly procured affordable generic versions of patented medicines through this mechanism, paying a fair royalty to the patent holder. Government and compulsory use licences have been used over 100 times to help facilitate access to affordable medicines throughout the world - including in Germany in 2017.

A Crown use licence would allow the NHS to procure a quality-assured generic version of Orkambi (lumacaftor-ivacaftor). We have secured quotes from some of the dozens of manufacturers supplying the two active pharmaceutical ingredients and, with help from experts, we've calculated that the generic price to the NHS could be less than £5,000. That's nearly £100,000 lower than Vertex's UK list price. We could treat every child that needs this drug and save the NHS nearly £4 billion over the next ten years.

With lives on the line, we believe every avenue to secure access should be pursued. We call on you to make a public commitment to explore a Crown use licence, whilst intervening to resume negotiations in a final attempt to secure a fair price from Vertex. If this fails the Government must enact the Crown use licence and make all the necessary arrangements to ensure a quality generic supply to the NHS.

We cannot stand by and allow our children to suffer and die when there is a medicine that can ease their condition. Cystic fibrosis patients' lives cannot be held to ransom by the profit-driven decision-making of a drug company. Neither can they be abandoned by their Government. You have a choice - put Vertex's monopoly at risk, or put our children's lives at risk. We believe the choice is simple.

Attached is some additional information outlining the context, background and considerations of this urgent situation. It includes analysis of Section 57A of the Patents Act which we believe should not be interpreted in a way that would render the Crown use mechanism ineffective through excessive payments to Vertex.

We hope to receive your confirmation very soon that Plan B will be actioned and ask for the opportunity to meet to discuss our campaign at the earliest opportunity. We look forward to working with you to achieve justice in this matter.

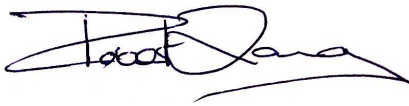
Yours sincerely,



Christina & Paul Walker  
Parents of a child with CF - Luis, aged 8



Nina & Daniel White  
Parents of a child with CF



Robert Long  
Parent of a child with CF



Gayle Pledger  
Parent of a child with CF



Emily Birchall  
Parent of a child with CF



Diarmaid McDonald  
Just Treatment

And three other parents of children with cystic fibrosis (CF) who need access to Orkambi but who wish to remain anonymous.