Legislation Details (With Text)

File #:	Res 0478-2018	**Version:**	*	**Name:**	Requires expanding access to breakthrough drugs for individuals with all serious diseases.
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Title:	Resolution calling on the United States Congress to pass, and the President to sign, a bill which requires expanding access to breakthrough drugs for individuals with all serious diseases.				
Sponsors:	Robert F. Holden				
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Attachments:	1. Res. No. 478, 2. August 8, 2018 - Stated Meeting Agenda with Links to Files, 3. Hearing Transcript - Stated Meeting 08-08-2018, 4. Minutes of the Stated Meeting - August 8, 2018				

Date	Ver.	Action By	Action	Result
8/8/2018	*	City Council	Introduced by Council	
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12/31/2021	*	City Council	Filed (End of Session)	

Res. No. 478

Resolution calling on the United States Congress to pass, and the President to sign, a bill which requires expanding access to breakthrough drugs for individuals with all serious diseases.

By Council Member Holden

Whereas, The United States (U.S.) Food and Drug Administration (FDA) defines a serious disease or condition as a disease or condition associated with morbidity that has substantial impact on day-to-day functioning, yet the morbidity need not be irreversible, provided it is persistent or recurrent; and
Whereas, Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one; and
Whereas, The FDA defines a "breakthrough drug" as one that is intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints; and
Whereas, The FDA will expedite the development and review of breakthrough drugs; and
Whereas, The FDA's Center for Drug Evaluation and Research (CDER) has received 64 breakthrough therapy designation requests since October 2017, and has granted 23 applications, including for a drug which helps individuals with cystic fibrosis and one for individuals with human immunodeficiency virus type 1 (HIV-1); and
Whereas, Thousands of New Yorkers are living with serious diseases; and
Whereas, According to the American Cancer Society, an estimated 110,800 New Yorkers across the state have been diagnosed with cancer in 2018; and
Whereas, According to the Department of Health (DOH), the crude rate of deaths resulting from all invasive

malignant tumors is 141.8 per 100,000 from 2011-2015 in New York City; and
Whereas, According to the Department of Health and Mental Hygiene (DOHMH), roughly 2,300 people were diagnosed with HIV in New York City in 2016; and
Whereas, In 2018, Congress passed and the President signed S.204, otherwise known as the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 or simply the Right to Try Act, which authorized the use of unapproved medical products by patients diagnosed specifically with terminal illnesses in accordance with State law by expanding access specifically to experimental drugs under certain conditions; and
Whereas, Individuals, including those with serious yet not terminal illnesses, should have access to breakthrough drugs; and
Whereas, In 2014, H.R.5805, sponsored by Rep. Michael McCaul, was introduced, and it called for a similar process to be created for breakthrough drugs, which treat individuals with both serious or terminal illnesses; and
Whereas, Under H.R.5805, a covered breakthrough drug refers to breakthrough drugs as well as products designated as fast track products, products which will have accelerated approval under section 506, qualified infectious disease products, or products with sponsors of which are awarded a priority review voucher; and
Whereas, Under Section 2 of H.R.5805, no later than 30 days after the date on which a drug meets the definition of a covered breakthrough drug, the sponsor of the covered breakthrough drug shall submit to the Secretary and make publicly available the policy of the sponsor with respect to requests submitted for use of said medication; and
Whereas, Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of set forth in Section 561 of the Federal Food, Drug, and Cosmetic Act, provide to such physician a breakthrough drug or breakthrough device for the diagnosis, monitoring, or treatment of a serious disease or condition; and
Whereas, Such a bill would expand access to medications which could assist individuals who would otherwise have no choice yet to wait for the medications to be approved; now, therefore, be it
Resolved, That the Council of the City of New York calls on the United States Congress to pass, and the President to sign, a bill which requires expanding access to breakthrough drugs for individuals with all serious diseases.

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