Legislation Details (With Text)

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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, Althea V. Stevens, Kalman Yeger				
Indexes:					
Attachments:	1. Res. No. 87, 2. March 24, 2022 - Stated Meeting Agenda, 3. Hearing Transcript - Stated Meeting 3-24-22, 4. Minutes of the Stated Meeting - March 24, 2022				

Date	Ver.	Action By	Action	Result
3/24/2022	*	City Council	Introduced by Council	
3/24/2022	*	City Council	Referred to Comm by Council	
12/31/2023	*	City Council	Filed (End of Session)	

Res. No. 87

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 Members Holden, Stevens and Yeger

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 therapy designation as a designation for a drug that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies; and

Whereas, The FDA will expedite the development and review of breakthrough drugs; and

Whereas, As of December 31, 2021, the FDA's Center for Drug Evaluation and Research (CDER) received 21 breakthrough therapy designation requests for Fiscal Year 2022, and has granted 5 applications; and

Whereas, Hundreds of thousands of New Yorkers are living with serious diseases; and

Whereas, According to the American Cancer Society, an estimated 118,830 New Yorkers across the state will be diagnosed with cancer, excluding basal cell and squamous cell skin cancers and in situ carcinomas except urinary bladder, in 2022; and

Whereas, According to the Department of Health (DOH), the annual death rate per 100,000 people from all invasive malignant tumors is 132.5 per 100,000 from 2014-2018 in New York City, averaging 12,537.6 deaths per year; and

Whereas, According to the Department of Health and Mental Hygiene (DOHMH), roughly 1,400 people were diagnosed with HIV in New York City in 2020; 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,

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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.

Session 12
EB
LS 1326
03.10.2022

Session 11
EB
LS 7173
Res. 0478-2018