

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

Twentieth Congress
First Regular Session

HOUSE BILL NO. 7438



Introduced by **Representative RAYMOND ADRIAN SALCEDA**

AN ACT

STREAMLINING ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICS, AND MEDICAL DEVICES FOR PATIENTS WITH LIFE-THREATENING OR SERIOUSLY DEBILITATING CONDITIONS, ESTABLISHING THE EXPANDED ACCESS AND RIGHT TO TRY FRAMEWORK, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Filipino patients facing life-threatening or seriously debilitating conditions often have limited treatment options. When approved therapies fail or are unavailable, these patients and their families are left with few alternatives. In many cases, investigational drugs, biologics, or medical devices that have shown promise in early clinical trials could potentially benefit these patients, yet access remains difficult due to regulatory hurdles.

The Philippines currently allows compassionate use of unregistered drugs through the Compassionate Special Permit (CSP) issued by the Food and Drug Administration (FDA) under Administrative Order No. 4, series of 1992, as amended. While this framework has been beneficial, the process remains cumbersome and time-consuming for critically ill patients who cannot afford delays. The documentary requirements, approval timelines, and lack of clear procedural guidelines often result in patients missing the window of opportunity for potentially life-saving treatments.

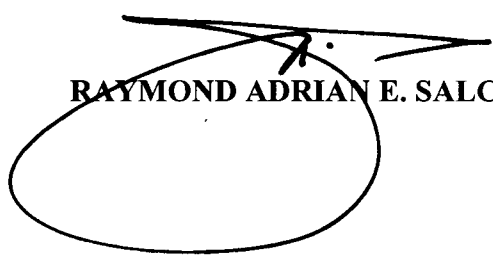
In 2018, the United States enacted the Right to Try Act, which streamlined access to investigational treatments for terminally ill patients who have exhausted approved treatment options. Similar frameworks exist in other jurisdictions, including Singapore's Special Access Route and Australia's Special Access Scheme. These frameworks recognize that for patients facing death or severe disability, the potential benefits of trying an investigational treatment may outweigh the risks of an unapproved therapy.

This bill seeks to establish a comprehensive Expanded Access and Right to Try framework in the Philippines. It streamlines the application process for compassionate use, establishes clear timelines for FDA action, provides for emergency access procedures, and creates liability

protections for physicians and manufacturers acting in good faith. The bill also ensures that patients receive adequate informed consent and that safety reporting mechanisms remain in place.

Importantly, this bill does not mandate that manufacturers provide investigational products, nor does it guarantee access. It simply removes unnecessary regulatory barriers and provides a clearer pathway for patients, physicians, and manufacturers who wish to pursue expanded access. Clinical trials remain the preferred pathway for accessing investigational treatments, as they provide the evidence needed to determine safety and efficacy for broader use.

The approval of this bill is earnestly sought.



RAYMOND ADRIAN E. SALCEDA

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RIGHT TO TRY FRAMEWORK, AND FOR OTHER PURPOSES**

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. *Short Title.* – This Act shall be known as the "Expanded Access and Right to Try Act."

SEC. 2. *Declaration of Policy.* – It is hereby declared the policy of the State to protect and promote the right to health of the people. Towards this end, the State shall provide a streamlined pathway for eligible patients with life-threatening or seriously debilitating conditions to access investigational drugs, biologics, and medical devices when approved treatment options have been exhausted, are unavailable, or are not suitable. The State recognizes that while clinical trials remain the preferred method for accessing investigational treatments, expanded access provides an important alternative for patients who cannot participate in clinical trials.

SEC. 3. *Definition of Terms.* – For purposes of this Act:

(a) "Eligible Patient" refers to a person who has been diagnosed with a life-threatening disease or condition, or a seriously debilitating condition, who has exhausted approved treatment options or for whom approved treatments are unavailable or unsuitable, and who is unable to participate in a clinical trial for the investigational product;

(b) "Life-Threatening Disease or Condition" refers to a disease or condition where the likelihood of death is high unless the course of the disease is interrupted, or a disease or condition with potentially fatal outcomes, where the end point of clinical trial analysis is survival;

(c) "Seriously Debilitating Condition" refers to a disease or condition that causes major irreversible morbidity or substantially impairs daily functioning;

(d) "Investigational Product" refers to any drug, biologic, or medical device that has completed Phase I clinical trials or equivalent testing demonstrating safety for human use, is currently under investigation in clinical trials, but has not yet received marketing authorization from the FDA;

(e) "Expanded Access" refers to the use of an investigational product outside of a clinical trial to treat a patient with a life-threatening disease or condition or seriously debilitating condition;

(f) "Manufacturer" or "Sponsor" refers to any person or entity that manufactures, produces, or is responsible for the development of an investigational product;

(g) "Treating Physician" refers to a physician licensed to practice medicine in the Philippines who is treating the eligible patient and who recommends the use of an investigational product;

(h) "FDA" refers to the Food and Drug Administration of the Philippines.

SEC. 4. *Eligibility Requirements.* – A patient shall be eligible for expanded access under this Act if:

(a) The patient has been diagnosed with a life-threatening disease or condition, or a seriously debilitating condition;

(b) The patient has exhausted approved treatment options, or approved treatments are unavailable, contraindicated, or have failed to produce adequate response;

(c) The patient is unable to participate in a clinical trial involving the investigational product, whether due to exclusion criteria, geographic inaccessibility, or other valid reasons;

(d) The potential benefit to the patient justifies the potential risks of the investigational product; and

(e) The patient, or the patient's legally authorized representative, has provided written informed consent.

SEC. 5. *Investigational Product Requirements.* – An investigational product shall be eligible for expanded access under this Act if:

(a) The product has successfully completed Phase I clinical trials or equivalent testing demonstrating that it is safe for human use;

(b) The product is currently under active clinical investigation; and

(c) The manufacturer or sponsor has agreed to provide the product for expanded access.

SEC. 6. *Streamlined Application Process.* – The FDA shall establish a streamlined application process for expanded access, which shall include:

- (a) A simplified application form that can be completed by the treating physician;
- (b) Electronic submission through the FDA's online portal;
- (c) Clear guidance documents explaining the application requirements and process;
- (d) A dedicated expanded access unit within the FDA to handle applications; and
- (e) A hotline and electronic communication channel for inquiries and assistance.

SEC. 7. *Timelines for FDA Action.* – The FDA shall act on expanded access applications within the following timelines:

- (a) For emergency individual patient requests: within twenty-four (24) hours from receipt of a complete application;
- (b) For non-emergency individual patient requests: within seven (7) working days from receipt of a complete application;
- (c) For intermediate-size patient populations: within fifteen (15) working days from receipt of a complete application;
- (d) For larger population expanded access protocols: within thirty (30) working days from receipt of a complete application.

Failure of the FDA to act within the prescribed timelines shall be deemed an approval of the application, unless the FDA notifies the applicant in writing of specific deficiencies that need to be addressed.

SEC. 8. *Emergency Access.* – In emergency situations where a patient faces imminent death or serious deterioration and there is insufficient time to submit a written application, the FDA shall allow treatment to commence upon telephone or electronic authorization from an FDA official. The treating physician shall submit a written application within five (5) working days following the emergency authorization.

SEC. 9. *Informed Consent.* – Prior to receiving an investigational product under this Act, the eligible patient, or the patient's legally authorized representative, shall provide written informed consent. The informed consent document shall include, at minimum:

- (a) A clear explanation that the investigational product has not been approved by the FDA and its safety and efficacy have not been established;
- (b) The known and potential risks and side effects of the investigational product;
- (c) The potential benefits and the probability of success;
- (d) Available alternatives, including palliative care and hospice;

(e) The costs involved and whether health insurance will cover such costs; and

(f) An acknowledgment that the patient understands that access to the investigational product is not guaranteed and that the manufacturer may decline to provide it.

SEC. 10. *Duties of Manufacturers.* – Manufacturers or sponsors who agree to provide investigational products under this Act shall:

(a) Provide the product in accordance with the terms agreed upon with the treating physician;

(b) Provide available information regarding the proper use, dosage, and administration of the product;

(c) Report any serious adverse events to the FDA within fifteen (15) calendar days; and

(d) Submit annual reports to the FDA summarizing expanded access activities and outcomes.

Nothing in this Act shall require a manufacturer to provide an investigational product for expanded access. The decision to provide or not provide an investigational product shall be at the sole discretion of the manufacturer.

SEC. 11. *Duties of Treating Physicians.* – The treating physician recommending expanded access shall:

(a) Certify that the patient meets the eligibility requirements under this Act;

(b) Ensure that the patient has provided informed consent;

(c) Administer or supervise the administration of the investigational product in accordance with good medical practice;

(d) Monitor the patient's response to treatment and report any adverse events to the FDA and the manufacturer; and

(e) Maintain accurate medical records of the expanded access treatment.

SEC. 12. *Liability Protection.* – No manufacturer, distributor, prescriber, dispenser, or other person or entity involved in the provision of an investigational product under this Act shall be liable for any harm caused to an eligible patient resulting from the use of such product, provided that:

(a) The patient provided informed consent as required under this Act;

(b) The product was provided and used in accordance with the terms of the expanded access authorization; and

(c) There was no willful misconduct, gross negligence, or reckless disregard for patient safety.

This liability protection shall extend to a manufacturer's decision not to provide an investigational product for expanded access.

SEC. 13. *Effect on Clinical Trials.* – Adverse events or outcomes observed in patients receiving investigational products under this Act shall not be used by the FDA as the sole basis for delaying or denying marketing approval of the product, unless such outcomes are directly attributable to the product's inherent properties rather than the patient's underlying condition.

SEC. 14. *Charging for Investigational Products.* – A manufacturer may charge for an investigational product provided under this Act, subject to the following conditions:

(a) The charge shall not exceed the direct costs of manufacturing the product, including raw materials, labor, and testing, plus reasonable overhead; and

(b) The manufacturer shall disclose the basis for the charge to the FDA upon request.

SEC. 15. *PhilHealth Coverage.* – The Philippine Health Insurance Corporation (PhilHealth) may include in its benefit packages the coverage of investigational products accessed under this Act for indigent and financially incapable patients, subject to guidelines to be issued by PhilHealth in coordination with the Department of Health.

SEC. 16. *Implementing Rules and Regulations.* – Within ninety (90) days from the effectivity of this Act, the FDA, in consultation with the Department of Health, PhilHealth, and relevant medical and patient advocacy organizations, shall promulgate the necessary rules and regulations to implement this Act.

SEC. 17. *Appropriations.* – The amount necessary to carry out the provisions of this Act shall be included in the annual General Appropriations Act.

SEC. 18. *Separability Clause.* – If any provision of this Act is declared unconstitutional or invalid, the other provisions not affected thereby shall remain in full force and effect.

SEC. 19. *Repealing Clause.* – All laws, decrees, orders, rules and regulations, or parts thereof, inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 20. *Effectivity.* – This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or in a newspaper of general circulation.

Approved,