

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

TWENTIETH CONGRESS
First Regular Session

HOUSE BILL NO. 6317



Introduced by: Hon. Keith Micah "Atty. Mike" D.L. Tan

AN ACT

AUTHORIZING THE DIRECTOR GENERAL OF THE FOOD AND DRUG ADMINISTRATION TO ISSUE EMERGENCY USE AUTHORIZATION, FURTHER AMENDING REPUBLIC ACT NO. 3720, OTHERWISE KNOWN AS THE "FOOD, DRUG, AND COSMETIC ACT," AS AMENDED BY REPUBLIC ACT NO. 9711, OTHERWISE KNOWN AS THE "FOOD AND DRUG ADMINISTRATION (FDA) ACT OF 2009"

EXPLANATORY NOTE

The 1987 Constitution mandates the State to protect and promote the health of the people and instill health consciousness among them (Article II, Section 15). The State is further mandated to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social service available to all the people at affordable cost (Article XIII, Section 11).

Republic Act No. 3720, otherwise known as the "Food, Drug and Cosmetic Act," as amended by the Executive Order No. 175., s. 1987, and the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009," mandate the Food and Drug Administration (FDA) to establish and maintain a drug regulatory system to ensure the purity, safety, efficacy and quality of drugs and vaccines in the country. Thus, the FDA is the sole agency authorized to regulate health products and issue authorization. Section 21 of R.A 3720, as amended, provided that any new drug should have an authorization from the FDA based on an application containing full report of investigations to show whether or not such drug is safe, efficacious and of good quality for use, based on clinical studies, prior to manufacture, sale importation, exportation, distribution or transfer thereof.

Considering that existing laws do not provide for the grant of EUA by the FDA, albeit Executive Order 121 granted the Director General of the FDA the authority to issue Emergency Use Authority for COVID-19 drugs and vaccines during the pandemic, such is a stopgap solution to the current inadequacy of our

laws to address the necessity of authorizing the FDA to issue EUA in the occasion of other public health emergencies.

Thus, this bill seeks to authorize the Director General of the Food and Drug Administration to issue an EUA to allow unapproved health products to be used during a public health emergency or a threat, to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved and available alternative health products, in order to enhance our pandemic preparedness and response.

It is hoped to expedite the availability of vaccines and therapeutics to people affected by any public health emergency and is based on essential set of available quality, safety, and efficacy performance data and ensure accelerated and smoother procurement and distribution of vaccines to the Filipino people during a public health emergency.

In view of the foregoing, the immediate passage of this measure is earnestly sought.

A handwritten signature in black ink, appearing to read 'Mike Tan', with a stylized flourish at the end.

Keith Micah "Atty. Mike" D.L. Tan
4th District, Quezon

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

SECTION 1. Section 10 of the Republic Act. No. 3720, as amended is hereby further amended to include new subsections (nn), (oo), (qq), and (rr) to read as follows:

"SEC. 10. For the purposes of this Act, the term:

xxx

"(NN) 'EMERGENCY USE AUTHORIZATION' MEANS THE AUTHORITY ISSUED BY THE FDA DIRECTOR GENERAL, ALLOWING UNAPPROVED HEALTH PRODUCTS TO BE USED DURING A PUBLIC HEALTH EMERGENCY OR THREAT, TO DIAGNOSE, TREAT, OR PREVENT SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS WHEN THERE ARE NO ADEQUATE, APPROVED AND AVAILABLE ALTERNATIVE HEALTH PRODUCTS. THE EMERGENCY USE MAY EITHER BE FOR AN UNAPPROVED HEALTH PRODUCT OR UNAPPROVED USE OF AN APPROVED HEALTH PRODUCT.

"(OO). 'UNAPPROVED HEALTH PRODUCT' MEANS A HEALTH PRODUCT THAT IS NOT APPROVED BY, LICENSED, OR REGISTERED WITH THE FDA AND, THEREFORE, NOT COVERED BY ANY PERMIT, LICENSE, CERTIFICATION, OR ACCREDITATION ISSUED BY THE SAID AGENCY FOR ITS MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, AND/OR WHERE APPROPRIATE, THE USE, TESTING,

PROMOTION, ADVERTISING, AND SPONSORSHIP THEREOF.

"(PP) 'UNAPPROVED USE OF AN APPROVED HEALTH PRODUCT' MEANS A HEALTH PRODUCT THAT IS APPROVED BY, LICENSED, OR REGISTERED WITH THE FDA BUT WHICH INTENDED EMERGENCY USE IS NOT AMONG THOSE APPROVED UNDER ITS CERTIFICATE OF PRODUCT REGISTRATION, MARKET AUTHORIZATION OR ANY OFFICIAL LICENSE ISSUED BY THE FDA.

"(QQ) 'PUBLIC HEALTH EMERGENCY' MEANS, PURSUANT TO REPUBLIC ACT NO. 11332, OTHERWISE KNOWN AS THE "MANDATORY REPORTING OF NOTIFIABLE DISEASES AND HEALTH EVENTS OF PUBLIC HEALTH CONCERN ACT," AN OCCURRENCE OR IMMINENT THREAT OF AN ILLNESS OR HEALTH CONDITION THAT:

"(1) IS CAUSED BY ANY OF THE FOLLOWING:

"(I) BIO TERRORISM;

"(II) APPEARANCE OF A NOVEL OR PREVIOUSLY CONTROLLED OR ERADICATED INFECTIOUS AGENT OR BIOLOGICAL TOXIN:

"(III) A NATURAL DISASTER;

"(IV) A CHEMICAL ATTACK OR ACCIDENTAL RELEASE;

"(V) A NUCLEAR ATTACK OR ACCIDENT; OR

"(VI) AN ATTACK OR ACCIDENTAL RELEASE OF RADIOACTIVE MATERIALS; AND

"(2) POSES A HIGH PROBABILITY OF ANY OF THE FOLLOWING:

(I) A LARGE NUMBER OF DEATHS IN THE AFFECTED POPULATION;

(II) A LARGE NUMBER OF SERIOUS INJURIES OR LONG-TERM DISABILITIES IN THE AFFECTED POPULATION;

(III) WIDESPREAD EXPOSURE TO AN INFECTIOUS OR TOXIC AGENT THAT POSES A SIGNIFICANT RISK OF SUBSTANTIAL HARM TO A LARGE NUMBER OF PEOPLE IN THE AFFECTED POPULATION;

(IV) INTERNATIONAL EXPOSURE TO AN INFECTIOUS OR TOXIC AGENT THAT POSES A SIGNIFICANT RISK TO THE HEALTH OF CITIZENS OF OTHER COUNTRIES; OR

(V) TRADE AND TRAVEL RESTRICTIONS;

"(RR) 'PUBLIC HEALTH THREAT' MEANS, PURSUANT TO R.A NO. 11332, ANY SITUATION OR FACTOR THAT MAY REPRESENT A DANGER TO THE HEALTH OF THE PEOPLE."

SEC. 2. A new Chapter XV and eight (8) new sections, Sections 38, 39, 40, 41, 42, 43, 44 and 45 shall be included to R.A No. 3720, as amended, which shall read as follows:

"CHAPTER XV EMERGENCY USE AUTHORIZATION

"SEC. 38. CRITERIA FOR THE ISSUANCE OF AN EUA. - THE ISSUANCE OF AN EUA UNDER THIS ACT BY THE FDA DIRECTOR GENERAL IS JUSTIFIED, ONLY IF, AFTER CONSULTATION WITH THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF SCIENCE AND TECHNOLOGY, AND OTHER CONCERNED GOVERNMENT AGENCIES, THE FDA DIRECTOR GENERAL CONCLUDES THAT:

"(1) A BIOLOGICAL, CHEMICAL, RADIOLOGICAL, OR NUCLEAR AGENT OR ANY AGENT THAT MAY CAUSE A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITIONS EXISTS;

"(2) BASED ON THE TOTALITY OF SCIENTIFIC EVIDENCE AVAILABLE TO THE FDA DIRECTOR GENERAL, INCLUDING DATA FROM ADEQUATE AND WELL-CONTROLLED CLINICAL TRIALS, IF AVAILABLE, IT IS REASONABLE TO BELIEVE THAT:

"i. THE HEALTH PRODUCT, FOR WHICH AN EUA WILL BE ISSUED, MAY BE EFFECTIVE IN DIAGNOSING, TREATING, OR PREVENTING SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION DURING A PUBLIC HEALTH EMERGENCY OR THREAT; AND

"ii. THE KNOWN AND POTENTIAL BENEFITS OF THE SAID HEALTH PRODUCT, WHEN USED TO DIAGNOSE, PREVENT, OR TREAT SUCH DISEASE OR CONDITION, OUTWEIGH THE KNOWN AND POTENTIAL RISKS OF THE PRODUCT;

"(3) THERE IS NO ADEQUATE, APPROVED, AND AVAILABLE ALTERNATIVE TO THE HEALTH PRODUCT FOR DIAGNOSING, PREVENTING, OR TREATING A DISEASE OR CONDITION DURING THE EXISTENCE OF A PUBLIC HEALTH EMERGENCY OR THREAT, AND

"(4) ALL REQUIREMENTS FOR THE ISSUANCE OF AN EUA UNDER THIS ACT AND OTHER PERTINENT REGULATIONS AND ISSUANCES ARE SATISFIED.

"SEC. 39. REPORT OF THE DIRECTOR GENERAL OF THE FDA. - THE FDA DIRECTOR GENERAL SHALL CONDUCT A SEPARATE AND INDEPENDENT DETERMINATION OF THE SAFETY AND POTENTIAL EFFECTIVENESS OF THE HEALTH PRODUCT AND THEREAFTER, ISSUE A REPORT ON SAID FINDINGS, PRIOR TO THE GRANT OF AN EUA.

"SEC. 40. CONTENTS OF THE AUTHORIZATION. - AN EUA ISSUED PURSUANT TO THIS ACT SHALL STATE:

"(1) EACH DISEASE OR CONDITION THAT THE HEALTH PRODUCT MAY BE USED TO DIAGNOSE, PREVENT, OR TREAT WITHIN THE SCOPE OF THE AUTHORIZATION;

"(2) THE FDA DIRECTOR GENERAL'S FINDINGS THAT THE KNOWN AND POTENTIAL BENEFITS OF THE HEALTH PRODUCT, WHEN USED TO DIAGNOSE, PREVENT, OR TREAT SUCH DISEASE OR CONDITION, OUTWEIGH THE KNOWN AND POTENTIAL RISKS OF THE PRODUCT; AND

"(3) THE FDA DIRECTOR GENERAL'S FINDINGS, CONCERNING THE SAFETY AND POTENTIAL EFFECTIVENESS OF THE HEALTH PRODUCT IN DIAGNOSING, PREVENTING, OR TREATING SUCH DISEASES OR CONDITIONS, INCLUDING, TO THE EXTENT PRACTICABLE, GIVEN THE CIRCUMSTANCES OF THE EMERGENCY, AN ASSESSMENT OF THE AVAILABLE SCIENTIFIC EVIDENCE.

"SEC. 41. APPLICATION FOR EUA. - AN APPLICATION FOR THE ISSUANCE OF AN EUA SHALL BE SUBMITTED BY THE INDUSTRY OR GOVERNMENT AGENCY CONCERNED, SUCH AS THE NATIONAL PROCURER OR THE PUBLIC HEALTH EMERGENCY IMPLEMENTER.

THE APPLICATION SHOULD DEMONSTRATE COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICES AND ACCOMPANIED BY AN UNDERTAKING BY THE MANUFACTURER TO COMPLETE THE DEVELOPMENT OF THE DRUG AND VACCINE, AMONG OTHERS.

"SEC. 42. DURATION OF AUTHORIZATION. - AN EUA UNDER THIS SECTION SHALL BE EFFECTIVE UNTIL THE TERMINATION OF THE DECLARATION OF PUBLIC HEALTH EMERGENCY ISSUED PURSUANT TO THE PRECEDING SECTION OR A REVOCATION AS PROVIDED FOR UNDER THE SUCCEEDING SECTION.

"SEC. 43. REVIEW AND REVOCATION OF AUTHORIZATION. - THE FDA DIRECTOR GENERAL MAY, WHEN NECESSARY, REVISE OR REVOKE AN EUA UPON THE OCCURRENCE OF ANY OF THE FOLLOWING CIRCUMSTANCES:

"THE FDA DIRECTOR GENERAL MAY, WHEN NECESSARY, REVISE OR

REVOKE AN EUA UPON THE OCCURRENCE OF ANY OF THE FOLLOWING CIRCUMSTANCES:

"(a) THE PUBLIC HEALTH EMERGENCY OR THREAT, AS MAY BE DETERMINED BY THE NATIONAL GOVERNMENT, NO LONGER EXISTS;

"(b) THE CRITERIA UNDER SECTION 39 OF THIS ACT FOR THE ISSUANCE OF AN EUA ARE NO LONGER SATISFIED; OR

"(c) OTHER CIRCUMSTANCES MAKE SUCH REVISION OR REVOCATION APPROPRIATE TO PROTECT PUBLIC HEALTH OR SAFETY.

"SEC. 44. EMERGENCY USE INSTRUCTIONS. - THE FDA SHALL, IN CONSULTATION AND COORDINATION WITH THE DOH, THE DOST, AND OTHER RELEVANT AGENCIES, ISSUE EMERGENCY USE INSTRUCTIONS TO INFORM HEALTH CARE PROVIDERS AND INDIVIDUALS, TO WHOM AN ELIGIBLE HEALTH PRODUCT UNDER THIS ACT IS TO BE ADMINISTERED, CONCERNING SUCH PRODUCT'S EUA."

"SEC. 45. POST-AUTHORIZATION MONITORING. - THE FDA, TOGETHER WITH OTHER CONCERNED OFFICES OF THE DOH, SHALL CONDUCT POST-AUTHORIZATION MONITORING TO TRACK PRODUCT DEVELOPMENT, ADDITIONAL RELEVANT INFORMATION, AND THE STATUS FROM THE MANUFACTURER CONCERNING FULL-PRODUCT LIFE-CYCLE. THE HOLDER OF AN EUA SHALL BE REQUIRED TO COMPLETE SPECIFIC PHARMACOVIGILANCE OBLIGATIONS, WITH A VIEW TO PROVIDING COMPREHENSIVE DATA CONFIRMING A POSITIVE BENEFIT-RISK BALANCE.

SEC. 3. Implementing Rules and Regulations. - The FDA shall formulate and issue guidelines, as may be necessary, for the effective implementation of this Act.

SEC. 4. Separability Clause. - If any provision of this Act is declared unconstitutional or invalid, other sections or parts thereof not affected thereby shall remain in full force and effect.

SEC. 5. Repealing Clause. - Except as otherwise expressly provided in this Act, all other laws, decrees, executive orders, proclamations, and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SEC. 29. Effectivity. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation.

Approved,