EIGHTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

Senate
Office of the Secretary

21 JAN 26 P3:42

SENATE
S. No. 2024

Introduced by Senator Francis "Tol" N. Tolentino

AN ACT

INSTITUTIONALIZING THE GRANT OF 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"; AND FOR OTHER PURPOSES

Explanatory Note

The Philippine government has announced its own vaccine deployment program, with the procurement of vaccines as the initial and crucial step. Negotiations to secure at least 148 million doses of COVID-19 vaccines from approximately seven companies are being discussed with the end goal of inoculating around 50 to 70 million Filipinos by the end of 2021.[1]

In its Press Statement dated 14 January 2021, the Philippine Food and Drug Administration (FDA) announced that it has granted an Emergency Use Authorization (EUA) to Pfizer-BioNtech's COVID-19 vaccine.[2] An EUA would allow procurement and use of an unregistered drug during the existence of a public health crisis.[3] To date, various COVID-19 vaccine candidates have already applied for and were granted EUAs by different countries. Several pharmaceutical companies, such as the UK firm AstraZeneca, Russian company

[1] https://cnnphilippines.com/news/2021/1/6/WHO-on-PH-COVID-19-vaccination-program.html
[2] https://www.fda.gov.ph/fda-philippines-grants-emergency-use-authorization-to-pfizer-biontech-covid-19-vaccine/
[3] Section 564 of the United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392, as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA).

Gamaleya Research Institute, Chinese drug maker Sinovac Biotech, and India-based firm Bharat Biotech,[4] have likewise sought the issuance of an EUA from the Philippine FDA.

Apparent from the foregoing is that a key requirement to any vaccine procurement plan and supply agreement is the grant of an authorization to use unregistered vaccines by the procuring government. In the Philippines, the FDA is the sole agency authorized to regulate health products and issue authorization under Section 4 of Republic Act (R.A.) No. 3720, otherwise known as "Food, Drug, and Cosmetic Act," as amended by R.A. No. 9711, otherwise known as the "FDA Act of 2009."

However, a reading of R.A. No. 3720, as amended, and its Implementing Rules and Regulations (IRR), do not provide for or contemplate the grant of EUA by the FDA. Despite the lack of authority, the FDA in recent months issued at least four (4) circulars, allowing for an EUA for COVID-19 drugs, to wit: *(i)* FDA Circular No. 2020-036, dated 14 December 2020; *(ii)* FDA Circular No. 2020-012-A, dated July 27, 2020; *(iii)* FDA Circular No. 2020-012-B, dated 26 August 2020; and *(iv)* FDA Circular 2020-012, dated 2 April 2020.

Although Executive Order (E.O.) No. 121, dated 1 December 2020, granted the Director General of the FDA the authority to issue EUA for COVID-19 drugs and vaccines, it could be argued that this is insufficient to clothe the said agency with the authority to do so. Under the Administrative Code of the Philippines, executive orders refer to acts of the President providing for rules of a general or permanent character in the implementation or execution of constitutional or statutory powers.[5] They cannot amend, revise, repeal, or in any way, alter what is stated under a law passed by Congress. As provided under Article 7 of the Civil Code of the Philippines, "[l]aws are repealed only by subsequent ones, and their violation or non-observance shall not be excused by disuse, or custom or practice to the contrary."[6]

Moreover, the provision on procurement of COVID-19 drugs and vaccines under Section 12 of Republic Act No. 11494, otherwise known as the "Bayanihan to Recover as One Act," neither authorizes the FDA Director General to grant EUA to pharmaceutical companies. Although the FDA and the Health Technology Assessment Council (HTAC) are empowered to

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[4] https://newsinfo.inquirer.net/1386482/indian-firm-seeks-eua-in-ph-for-its-covid-19-vaccine-covaxin#ixzz6kBXTIV6N

[5] Section 2, Chapter 2, Book III of Executive Order No. 292, otherwise known as the "Administrative Code of 1987."

[6] Article 7, Republic Act No. 386, otherwise known as the "Civil Code of the Philippines."

determine the minimum standards for the distribution of medications and vaccines,[7] the said Act did not contemplate granting the FDA the authority to issue EUA for the procurement of COVID-19 vaccines.

This glaring void in the law deems the FDA's issuances on EUA and the grant thereof to COVID-19 vaccine manufacturers subject to stricter legal scrutiny. They may be declared void if found to be in excess of the authority conferred or in conflict with the governing statute. Invalidating the EUA issuances and grants, however, in time of a public health crisis would be an impractical thing to do. It would result in unnecessary delays in the deployment of the much-needed COVID-19 vaccines for the Filipinos.

Hence, in order to address the lack of authority to grant EUA under the existing FDA law, this Bill seeks to further amend R.A. No. 3720 in order to define EUA and provide the parameters for its issuance. The proposed measure not only gives legitimacy to the circulars issued by the FDA on EUA but also ensures the faster and smoother procurement and distribution of vaccines to the Filipino people during a public health emergency.

In light of the foregoing, the passage of this bill is earnestly sought.

FRANCIS "TOL" N. TOLENTINO
Senator

[7] Section 12 of Republic Act No. 11494, otherwise known as the "Bayanihan to Recover as One Act."

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

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

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

XXX

(NN) EMERGENCY USE AUTHORIZATION (EUA) REFERS TO 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 (R.A.) 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."

Section 2. A new Chapter XV and six (6) new sections, Sections 38, 39, 40, 41, 42, and 43 shall be introduced to R.A. No. 3720, as amended, which shall read as follows:

"CHAPTER XV

EMERGENCY USE AUTHORIZATION

SEC. 38. *SCOPE OF 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. 39. *CRITERIA FOR 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 CONDITION 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. 40. *DECLARATION BY THE DIRECTOR GENERAL OF THE FDA.* - THE FDA DIRECTOR GENERAL SHALL CONDUCT A SEPARATE AND INDEPENDENT DETERMINATION AND, THEREAFTER, ISSUE A DECLARATION ON SAID FINDINGS, PRIOR TO THE GRANT OF AN EUA. THE DETERMINATION AND DECLARATION SHALL BE SEPARATE FROM THE DECLARATION OF A PUBLIC HEALTH EMERGENCY BY THE

NATIONAL GOVERNMENT. LIKEWISE, THEY SHOULD SATISFY THE CRITERIA ENUMERATED UNDER THE IMMEDIATELY PRECEDING SECTION AND ALL OTHER REQUIREMENTS PROVIDED FOR BY THIS ACT.

SEC. 41. *DURATION OF AUTHORIZATION.* - AN EUA UNDER THIS SECTION SHALL BE EFFECTIVE UNTIL THE TERMINATION OF THE DECLARATION ISSUED PURSUANT TO THE PRECEDING SECTION OR A REVOCATION AS PROVIDED FOR UNDER THE SUCCEEDING SECTION.

SEC. 42. *REVIEW AND REVOCATION OF AUTHORIZATION.* - THE FDA DIRECTOR GENERAL SHALL PERIODICALLY REVIEW THE CIRCUMSTANCES AND THE APPROPRIATENESS OF ALL EUA ISSUED PURSUANT TO THIS ACT.

THE FDA DIRECTOR GENERAL MAY, WHEN NECESSARY, REVISE OR REVOKE AN EUA UPON THE OCCURRENCE 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. 43. *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."

Section 3. *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.

Section 4. *Repealing Clause.* - All laws, decrees, executive orders, rules, and regulations, or parts thereof, inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Section 5. *Effectivity Clause.* - This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or in at least one (1) newspaper of general circulation.

Approved,