Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 1102

Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT
INSTITUTING THE FOOD AND DRUG ADMINISTRATION AS AN INDEPENDENT AGENCY, AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED BY REPUBLIC ACT NO. 9711

EXPLANATORY NOTE

The Food and Drug Administration (FDA) plays an important role in the functioning of an efficient and responsive health system of the country that has been found to be among the biggest underachievers in Asia when it comes to healthcare mainly due to less funding than required for the size of the population and economy or other administrative circumstances.

The Department of Health has opined that the reason for the country's underachievement in healthcare may be attributed to the fragmentation of the health system due to a large and difficult to regulate private sector[1].

The FDA functions as one of the primary regulatory bodies in the gamut of health governance, regulation being one of the essential governance mechanisms that is particularly important for transitional Asian economies experiencing major changes to their health systems like the Philippines[2].

Part of the health regulations are embodied under Republic Act No. 9711, which provides for the policy of protecting and promoting the right to health of the Filipino people by ensuring the safety, efficacy, quality and purity of foods, drugs, devices and cosmetics; and the establishment and maintenance of an effective health products regulatory system responsive to the country's health needs and problems.

Presently, the FDA functions under the Department of Health (DOH) where instances of potential conflicts of interest have been noted. This organizational design undermines the independence and autonomy of the FDA in its decision process and gives rise to undue politicking. Hence, in order to enhance the regulatory capacity and strengthening of FDA's capacity with regard to the inspection, licensing and monitoring of establishments and their registration and monitoring of health products, this bill seeks to separate the FDA from the DOH thereby making it an independent and autonomous office attached to the Office of the President.

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[1] PH an 'underachiever' in health care, (Ben Kritz, TMT, Manila Times, May 23, 2017, http://www.manilatimes.net/ph-underachiever-health-care/328740/)
[2] Effective Regulations in health Systems, Hervic Teams, University of Leeds (UK), Royal Tropical Institute (Netherlands) et. al)

An autonomous and independent FDA paves the way for the establishment of clear lines of responsibility and accountability and ensure the availability of healthy food, drugs, cosmetics, medical devices and household products in the market.

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

ANGELINA "HELEN" D.L. TAN, M.D.
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 4 of Republic Act No. 3720, as amended by Section 5 of Republic Act No. 9711, is hereby further amended to read as follows:

"SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) **[**in the Department of Health (DOH)**]**. **THE FDA SHALL BE AN INDEPENDENT AND AUTONOMOUS AGENCY ATTACHED TO THE OFFICE OF THE PRESIDENT AND SHALL EXERCISE THE FOLLOWING FUNCTIONS, POWERS AND DUTIES**: **[**Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:**]**

"(a) To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;

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SEC. 2. Section 6 of Republic Act No. 3720, as amended by Section 7 of Republic Act No. 9711, is hereby further amended to read as follows:

"(a) The FDA shall be headed by a director-general, with the rank of undersecretary, who shall be tasked, among others, to determine the needed personnel and to appoint personnel, below the assistant director level **[**in coordination with the Secretary of Health**]**."

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"(h) Each center and field office shall be headed by a director who shall be assisted by an assistant director. These directors shall be appointed by the **[**Secretary of Health**]** **DIRECTOR-GENERAL**.

SEC. 3. Section 7 of Republic Act No. 3720, as amended by Section 8 of Republic Act No. 9711, is hereby further amended to read as follows:

"The FDA shall review its staffing pattern and position titles subject to the approval of the **[**Secretary of Health**]** **PRESIDENT**."

SEC. 4. Section 32 of Republic Act No. 3720, as amended by Section 15 of Republic Act No. 9711, is hereby amended to read as follows:

"SEC. 32. The orders, rulings or decisions of the FDA shall be appealable to the **[**Secretary of Health**]** **OFFICE OF THE PRESIDENT**. An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.

"An appeal shall not stay the decision appealed from unless an order from the **[**Secretary of Health**]** **OFFICE OF THE PRESIDENT** is issued to stay the execution thereof."

SEC. 5. Section 34 of Republic Act No. 3720, as amended by Section 17 of Republic Act No. 9711, is hereby further amended to read as follows:

"SEC. 34. Fees and Other Income. -

"(a) Upon the sole approval of the **[**Secretary**]** **PRESIDENT**, the authorization and other fees shall annually be determined and reviewed by the FDA and any proposed increase shall be published in two (2) leading newspapers of general circulation.

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"(c) The Director-General of the FDA, upon approval of the **[**Secretary**]** **PRESIDENT**, shall be authorized to promulgate rules and regulations governing the collection of the 'other related regulatory fees'. Upon approval of the **[**Secretary**]** **PRESIDENT**, these fees shall likewise be reviewed periodically and any proposed increase shall be published in two (2) leading newspapers of general circulation."

SEC. 6. Section 18 of Republic Act No. 9711 is hereby amended to read as follows:

"SEC.18. All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a special regulatory fund. Any interest earned by such fund shall form part of the retained income. Such fund shall be used primarily for the acquisition of office and laboratory space, human resource development and expansion, purchase of laboratory equipment and motor vehicles, the upgrading of its current facilities and equipment and maintenance, other operating expenses of the central office laboratory divisions and satellite laboratories in Davao, Cebu and other testing laboratories, in case the above .laboratories will be increased, and other activities or services of the agency in the performance of its mandate.

The fund shall be allowed to accept grants, donations and all other endowments from local and external sources in accordance with pertinent laws, rules and regulations.

The retention, use and application of this fund shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from

any executive office, but will be subject only to the general accounting rules and guidelines by the Commission on Audit (COA). The primary purpose of the fund as herein stated shall prevail over any other purpose that may be pursued by the FDA on its own initiative or through an order or directive by any higher office. The FDA shall submit to the **[**Secretary of Health**]** **PRESIDENT**, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 23 of this Act, a report on how the funds were utilized, including its accomplishments."

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SEC. 7. Section 35 of Republic Act No. 3720, as amended by Section Republic Act No. 9711, is hereby further amended to read as follows:

"SEC. 35. The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, calibrate, assay and examine samples of health products. For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have the necessary and appropriate state-of-the-art laboratory equipment and personnel complement. The main testing laboratories at the central office shall be maintained and shall serve as a support unit to the centers for product research and evaluation and standards development and shall serve as testing centers that would include assay and the conduct, supervision, oversight and/or audit of bioequivalence and bioavailability test/researches, among others. The existing laboratories in Cebu and Davao will be upgraded and transformed as quality assurance laboratories, while another one will be established in Subic, Zambales.

"The testing laboratories may be increased by the director-general, upon approval of the **[**Secretary**]** **PRESIDENT**. Moreover, the director-general, upon approval of the **[**Secretary**]** **PRESIDENT**, may call upon other government and private testing laboratories to conduct testing, calibration, assay and examination of samples of health products: Provided, That the private testing laboratories are accredited by the Philippine Accreditation Office (PAO) of the Department of Trade and industry (DTI) and the **[**DOH**]** **FDA**."

SEC. 8. Section 37 of Republic Act No. 3720, as amended by Section Republic Act No. 9711, is hereby further amended to read as follows:

"SEC. 37. The FDA, with the approval of the **[**Secretary**]** **PRESIDENT**, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards. There shall be created additional plantilla positions to augment the human resource complement of the FDA, subject to existing rules and regulations."

SEC. 9. *Repealing Clause*. - All laws, decrees, executive orders or parts thereof inconsistent with the provisions of this Act are hereby repealed, amended or modified accordingly.

SEC. 10. *Effectivity Clause*. - This Act shall take effect fifteen (15) days after its complete publication in the Official Gazelle or in a national newspaper of general circulation.

Approved,