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SENATE

RECEIVED BY: 

P.S. R. NO. 381

Introduced by SENATOR EDGARDO J. ANGARA

**RESOLUTION ALLOWING THE GENERIC PRODUCTION OF TAMIFLU
DRUG BY INVOKING THE COMPULSORY LICENSING CLAUSE IN
BOTH INTERNATIONAL AND DOMESTIC PATENT LAWS AS BOTH A
PREVENTATIVE AND ADAPTIVE RESPONSE TO THE
AVIAN INFLUENZA PANDEMIC THREAT**

- WHEREAS,** Birds get flu every year. Normally, this poses minimal danger to other birds and none to humans. In contrast, of the 15 avian influenza virus subtypes, the **H5N1 variant** today is devastatingly lethal, for reasons not fully understood, to many bird species and has infected people;
- WHEREAS,** After incubating for eight (8) years in East Asia, killing 140 million birds (including those intentionally destroyed to stop its spread), the H5N1 flu strain abruptly and mysteriously expanded its range this year, north to Mongolia and Siberia, then west into Ukraine, Croatia and Turkey;
- WHEREAS,** Experts are concerned that the avian flu has completed two of the three steps needed for a pandemic: It is a deadly strain to which no humans have immunity, and it has crossed the species barrier from chickens almost intact. The final step would be a fatal mutation that allows it to move from human to human;
- WHEREAS,** The World Health Organization (WHO) declared that a human pandemic of bird flu is now only a matter of time. As of this week, it knows of 138 people who have been infected, 68 of whom have died;
- WHEREAS,** The Asian Development Bank (ADB) outlined a number of scenarios in the event of a global flu outbreak: Asia alone could lose almost \$282.7 billion in consumption, trade and investment and another \$14.2 billion from workers' incapacity and death. "Growth in Asia would virtually stop," and the economic impact would probably force the world into a prolonged recession.

Depending on the effectivity of the virus, worldwide toll could be between 7.4 and 150 million deaths;

WHEREAS, Dr. Margaret Chan, WHO head of pandemic-flu preparedness notes that “in history no human intervention has managed to stop a pandemic once it starts.” The key factors for success in controlling a local outbreak before it gets loose are: surveillance, quarantine measures, availability of vaccines and antiviral drugs, and the state of readiness in hospitals;

WHEREAS, Currently, antiviral agents are the only medical intervention available for H5N1-affected patients, *to wit:* tablet form oseltamivir (Tamiflu) and inhaler preparation zanamivir (Relenza). These are relatively scarce resources as it is under patent by F Hoffman-La Roche pharmaceutical company until 2016.

WHEREAS, The Doha Declaration on the TRIPS Agreement and Public Health (9-14 November 2001) allows:

Each Member ... the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted... [as well as] the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

These provisions allow governments to cope with a public health emergency by waiving the patent rights of a private company and allowing generic copies of a drug to be made and are aimed at helping developing countries to provide essential drugs to impoverished populations at a more affordable price.

WHEREAS, Section 93 of RA 8293 or the Intellectual Property Code of the Philippines adopts substantially the abovementioned DOHA Declaration on compulsory licensing;

WHEREAS, Bringing into play the compulsory licensing clause would allow Philippine generic manufacturers to start producing antivirals locally or import them from generic producers at marginal costs. This, in turn, would help establish our national pandemic stockpile in a timely and affordable manner as the country’s first-line of defense against the avian flu threat;

WHEREAS, Although the WHO has stockpiled 3m doses of oseltamivir for global use, this stockpile is not and cannot be a substitute for national preparedness and stockpiling by each nation.

To date, many developed countries have reportedly stockpiled 10-dose courses of Tamiflu to cover 20%-40% of their populations: USA (20 million packages of 10); Canada (1.6 million); United Kingdom (14.6 million); Australia (3.9 million); Norway (1.4 million) and New Zealand (0.8 million).

WHEREAS, Aside from addressing regulatory and other legal barriers to the expansion of domestic vaccine /antiviral production and importation capacity, the Philippine government must commit P 2 Billion for the purchase of Tamiflu flu drug to cover at least 10% of the population for rapid response;

WHEREAS, At this time of worldwide pandemic alertness, Philippines should also seek greater measures to stop this disease in its tracks, at its source, which is in animals, by seeking active cooperation with countries that have had outbreaks of the H5N1 avian influenza strain and are likely sources of a pandemic like Vietnam, Laos, Cambodia, Hongkong, Indonesia, Thailand, and China to ensure optimal pandemic preparedness;

WHEREAS, The fate of the world, and the country, hung in the balance between the forces of mutation and natural selection, and the preparations undertaken by governments.

RESOLVED, AS IT IS HEREBY RESOLVED, That the Philippine government should: 1) move for the application of the compulsory licensing clause in our patent laws to allow the generic production of Tamiflu for the country's emergency antiviral stockpile as both a preventative and adaptive mechanism to address the avian influenza pandemic threat; 2) express public and strong support for countries in the region taking the compulsory licensing route; 3) raise the issue of a coordinated approach to generic manufacture in the region; and 4) ensure that our national stockpile are properly adjusted to the diversity of medical requirements during a pandemic, including personal protective equipment, antibiotics and general supplies.

BE IT FURTHER RESOLVED, AS IT IS HEREBY RESOLVED, That the Philippine government, as a matter of national urgency, establish a Bird Flu Pandemic Capability and Preparedness Committee, spearheaded by the Department of Health (DOH) and the Department of Agriculture (DA), that will involve both public and private sector participation in crafting, coordinating, implementing, and supervising containment and response strategies to address a major public health crisis like the H5N1 bird flu virus.

Adopted,


EDGARDO J. ANGARA
Senator