TOPIC:

Several companies want to donate "rapid CO-VID 19 test kits" made in China, Korea & other countries to our hospitals. However, it turns out that the hospitals cannot use the kits (even if they wanted to) because they have not been "approved" by FDA. Neither have they been recommended by the DOH.

Question : can the hospital + doctor/s be criminally charged if they are caught administering these rapid test kits on their patients?

Selling or "peddling" consumer products may not be easy as you think it is, especially if you are dealing with health products such as food, drug, cosmetic, medical devices, and household urban/hazardous substances. Months ago, the supply of these products may be abundant from the supermarket or grocery store. With the enhanced community quarantine, however, it is another story. These products may be scarce now and sellers are now "regulating" the retail of these hard-to-find commodities due to high demand or panic resulting to hoarding.

Test kits for COVID-19 fall as a "health product" as defined by law.

The government has the power to regulate these commodities classified as "health product" under Republic No. 9711 (also known as the "Food and Drug Administration Act of 2009"). The regulator in charge of regulating these commodities is Food and Drug Administration or FDA. Two important reasons why regulation is needed: Consumer protection and Supplier accountability.

<u>Consumer Protection</u>
A conscious consumer would not buy or use a product that has not tested and approved. Moreso use such a product if it would leave with him without any remedy against the supplier in case something goes wrong, like, experiencing negative side effects, for example. Like in our current scenario when the buyer of a seemingly okay COVID-19 test kit celebrates after learning that he is "COVID-19 free" by launching a hugging spree with his loved ones, only to later on find out that it was actually a "false negative" finding and infecting everybody altogether.

This is in the same manner that a prudent hospital owner or a trusted healthcare professional or clinic would not allow the use, or administration of a health product that has not been tested, cleared and registered as "approved" by the appropriate government agency—in this case, the FDA—without remedy against the supplier in case of adverse effect after use, consumption or administration.

COVID-19 test kits are specifically considered as "medical devices". Under Republic No. 9711, medical device means "any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention,, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body."

COVID-19 test kit thus comes within the regulatory jurisdiction of the FDA being an instrument to help determine the existence of the corona virus in a human being.

In a nutshell, the FDA does two things to protect the consumer:
First, it issues a license to an entity that is willing to deal with regulated products, and *second*, it issues an authorization to the entity to market regulated products. Both license and authorization are issued upon the applicant's compliance with stringent regulatory requirements of the FDA, which are put in place to ensure the quality, safe and effectiveness of health products sold in the market.

For COVID-19 test kits, the FDA requires the supplier to have an authorization to deal in with medical devices in the form of a *License to Operate* or LTO for "medical devices". The licensed supplier must then submit the technical (vetting) requirements for the registration of the kit itself.

Without these authorizations, acceptance by the Department of Health (DOH) and post-importation exam by the FDA, the donated COVID test kits especially those coming from other countries may not be placed in the stock rooms of stores or hospitals. Those which pass through the Philippine borders without these authorizations which may have ended up in the stock rooms of clinics or hospitals, may be said to have been entered illegally into the country.

<u>Supplier accountability</u>
The illegal distribution of test kits without these required authorizations is punishable under the law. Suppliers, manufacturers, importers, and distributors of health products without securing these authorizations may suffer the penalty of of imprisonment from one (1) year to ten (10) years or a suffer a fine of at least Fifty thousand pesos (P50,000.00) to Five hundred thousand pesos (P500,000.00), and Five Million Pesos (5,000,000,00). The law covers penalizing those who would manufacture, import, export, sell, offer for sale,

distribute, transfer, promote, advertise, or sponsor any health product that is "adulterated, unregistered or misbranded".

Clearly, owners of clinics or hospitals which may have been supplied of illegal test kits from the "gray market" would also be exposed to the same penalties if they too, will engage in the "trade" of the product. Meanwhile, for healthcare professionals who may have administered the use of these "unregistered" COVID-19 test kits may be given the favor of liberality of the law and may not be held criminally liable for such violation.

Hospitals and medical staff using these unregistered products may also jeopardize its License to Operate (LTO) as granted by the DOH Health Facilities and Services Regulatory Bureau (HSFRB), for Violation of another related law, RA 4226 or the Hospital Licensure Act. To make matters worse, the healthcare professional may also lose his license under the provisions of the charter of his profession under the radar of the Professional Regulation Commission [PRC]). Such healthcare professional may also be prosecuted for criminal imprudence or negligence under Article 365 of the Revised Penal Code for the damage or injury to the person on whom the CO-VID test kit was used or administration, and/or any damage or injury reasonably connected with such administration.

It is all about making the right choices. In times like these, it pays to be on the side of caution by following government directives including awaiting for regulatory approvals regardless of personal opinions and beliefs. Government reform like lessening regulatory requirements or shortening the process in cases of pandemic or other emergency cases may be taken into consideration based from our very own experience. And this is another story to tell altogether.

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