

**SUBJECT : REPORT ON THE PUBLIC HEARING OF THE COMMITTEE ON HEALTH & DEMOGRAPHY ON PSR 40, TO INVESTIGATE THE ALLEGED PROLIFERATION OF COUNTERFEIT MEDICINES ON OCTOBER 6, 2004, 9:30 A.M. AT THE SEN. PECSON ROOM, SENATE OF THE PHILIPPINES**

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**I. PRELIMINARY**

Sen. Cayetano, Chairperson of the Committee on Health and Demography, called the meeting to order at 9:43 a.m. In attendance were Senators Flavier and Lapid. The resource persons invited to shed light on the problem of counterfeit medicines in the market are the following:

Dr. Leticia Gutierrez – Director, Bureau of Food and Drugs (BFAD)  
Atty. Emil Polig – Legal Officer, BFAD  
Nancy Lanuza – Chief, RDI, BFAD  
Atty. Francis Borja, Jr., - Pharmaceutical and Healthcare Association of the Philippines (PHAP)  
Frances Romina T. Mendiola – Executive Director, Philippine Chamber of the Pharmaceutical Industry, Inc.  
Josephine Inocencio – Drugstores Association of the Philippines  
Ramon Salazar – Director, Customs Intelligence and Investigation Service, Bureau of Customs  
Olivia Ocaña – Department of Trade and Industry  
Atty. Anthony Robert A. Abad – President, Philippine International Trading Corporation (PITC)

**II. HIGHLIGHTS**

Dr. Leticia Gutierrez, Director of the Bureau of Food and Drugs (BFAD) gave a background on the problem of counterfeit drugs in the country. There are three laws that specifically protect the consumers from counterfeit or fake drugs: (1) RA 3720, “Food, Drug and Cosmetics Act;” (2) RA 7394, “Consumer Act of the Philippines” and; (3) RA 8304, “Special Law on Counterfeit Drugs.” These laws require that drugs/medicines must be registered with the BFAD before these can be manufactured, imported, exported, sold, offered for sale and distributed in the Philippines. It is BFAD’s duty to examine and evaluate the drug’s safety, efficacy and quality before issuing a certificate of product registration. To do this, BFAD conducts monitoring and surveillance of products in the market, including suspected counterfeit drugs.

However, BFAD’s all out campaign against fake drugs is hampered by its lack of financial resources and personnel. Dr. Gutierrez pointed out that aside from drugs, BFAD is also in charge of ensuring the safety and quality of food and cosmetics and is tasked to implement provisions of several laws on food fortification, salt iodization and tobacco regulation among others. Despite its many responsibilities, BFAD has only 150 food and

drug regulation officers (40 in Metro Manila and 114 in 15 regions) to inspect and monitor 39,000 establishments and 55,000 products. BFAD's budget has even gone down from P195 M in 2002 to P120 M in 2003 and 2004. To enable BFAD to perform well, it is proposing that the government allow the agency to utilize one hundred percent of its collected regulatory fees to augment its annual budget. The extra income would mean additional personnel and upgraded facilities. In 2003, BFAD collected P126 M but the Department of Budget and Management (DBM) only allowed the agency to retain P5 M or about four percent of its income.

To address BFAD's lack of personnel, Sen. Lapid proposed that BFAD collaborate with the local government units (LGUs) especially in the surveillance of fake medicines at the local level. Being a former governor himself, Sen. Lapid was certain that each LGU would be more than willing to provide BFAD with one personnel under the LGU payroll to help BFAD perform its duties. In the same vein, Sen. Flavio urged BFAD to be more proactive in solving its problems and not just wait for additional resources from the national government. He suggested, for instance, that BFAD deputize the Philippine Drug Enforcement Agency (PDEA) to seize counterfeit drugs in the market.

Sen. Cayetano, while sympathetic to BFAD's problems and is supportive of the proposal to augment BFAD's resources, scolded the agency for not implementing the full strength of the law on counterfeit drugs. She cited that based on BFAD records, no drugstore caught selling fake drugs had been punished with the highest penalty of permanent closure as provided in RA 8304. According to Sen. Cayetano, to curb the proliferation of fake medicines, BFAD must be strict and firm in meting out the penalties provided in the law to erring establishments. Moreover, she criticized the Bureau of Customs for its failure to apprehend large amounts of smuggled medicines entering the country. Based on RA 8304, medicines without BFAD registration are considered fake medicines. She deplored the Bureau of Customs record of only three apprehensions of passenger bags containing medicines without BFAD registration vis-à-vis the reported P7.2 B problem of fake drugs in the country.

Atty. Abad of the PITC assured the Committee of the safety and quality of the low-priced medicines under the government's parallel importation program. Under Executive Order 85, the PITC is authorized to import medicines from India and to sell

these in government hospitals at a much lower price than prevailing price in the market. Responding to the concern that the parallel importation has opened the floodgates to the entry of fake medicines, Atty. Abad said that PITC is still required to undergo registration requirements and the imported medicines are subjected to testing. According to him, the PITC runs a tight ship, they are able to monitor where their medicines go because of the special stickers they place on the boxes. Furthermore, their market is limited and they only import a limited quantity, P120 M in 2002 and only P40 M in 2004.

The drug industry represented by the Philippine Pharmaceutical Association of the Philippines, an organization of multinational drug companies and the Chamber of the Pharmaceutical Industry, Inc., an association of Filipino drug manufacturers expressed their cooperation and support to BFAD's efforts to curtail the sale of fake drugs. PHAP, in particular, is also doing their own surveillance of fake drugs in the market and coordinates with BFAD in curtailing its sale. In fact, PHAP together with the Department of Health is embarking on a nationwide information campaign on counterfeit drugs. The Drugstores Association of the Philippines also articulated that they are constantly coordinating with BFAD in policing their own ranks and they immediately report to BFAD violations of the law committed by any member of their organization.

The hearing was adjourned at 11:52 a.m.