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Inside story on the Tetanus Toxoid debacle:
**FERTILITY REGULATING VACCINES &
THE NATIONAL IMMUNIZATION
PROGRAM**

**Letter by Dr. Angelita Miguel-Aguirre of the
Makati Medical Society & Philippine Medical
Association
Presented for info by the PhilFam Committee
22 May 1998**

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August 17, 1996
MRS. LETTY JIMENEZ-MAGSANOC
Editor-in-Chief
Inquirer

Dear Mrs. Magsanoc,

It is quite unfortunate that an important issue such as the tetanus toxoid controversy is dealt with in media with simple press releases in favor or against personalities, and opinionated dissertations of newspaper columnists. There seems to be no attempt at all on the part of certain journalists to look into the facts and scientific data about the issues presented.

Here are some facts:

The concern about the purity of the tetanus toxoid

vaccines used in the "massive" immunization program of the DOH at the time was not at all without basis. The alert bulletin was sent to the responsible groups in the Philippines by COMITE NATIONAL PRO-VIDA of Mexico and subsequently similar concerns also came from Nicaragua. At that time therefore, questionnaires were distributed to patients in various communities in the country to look into the untoward side effects experienced by those who were given the vaccines. There was also great concern about the manner by which the vaccine in question was being administered. There were field workers who were giving it indiscriminately.

Because of the seriousness of the allegations which affect the health of Filipinos on the national level, the Philippine Medical Association formed an AD HOC Committee on the Tetanus Toxoid Controversy to study the matter. The Physicians reviewed over 25 published research works on contraceptive vaccines which has been going on since 1975 and one of the groups at the forefront of this is that of Dr. G.P. Talwar from New Delhi who has been conducting the study on women in India. A telephone interview with him was brought to our attention wherein he expressed the opinion that he did not consider the vaccine as an abortifacient because he feels that life begins at implantation and NOT AT FERTILIZATION. (We have enclosed the paper which was received by fax from Brown University written by Vernon Stevens, PhD because it elucidates clearly how contraceptive vaccines work.)

After various deliberations and data gathering, the AD HOC Committee formed by the PMA came up with a position paper which was presented to the Department of Health (photocopy enclosed). Committee representatives met with responsible officials of the DOH At San Lazaro Compound to discuss the observations and issues raised in the PMA position paper in the presence of a WHO representative (Dr. Rudolf H. Tangermann, M.D., Medical Officer; Expanded Program on Immunization, Regional Office for the Western Pacific -- WHO).

1.) on the issue of whether the B sub-unit of HCG is present in the tetanus toxoid vaccine used in the NID campaign in 1993 -- the officials of the DOH subsequently agreed to join hands with PMA to conduct the tests on the vials in question in an independent and competent laboratory, the results of which is yet to be known and subsequently to be announced.

Questions raised -

2.) What was the need for massive immunization of women ages 15 to 44 years old when the incidence of tetanus is low and NOT in epidemic proportions as shown by the data

from the Philippine Health Statistics issued by the DOH?

There were public pronouncements made that here were 25 babies dying from tetanus neonatorum (tetanus in the newborn -- up to 4 weeks old) everyday which would mean that there were 9125 babies dying from the disease every year! -- yet the above reference disclosed that in 1990 the mortality in all ages is 989 and 695 of them were MEN with an overall incidence of 1 per 100,000. Under one year old the mortality was 172. In 1991 the mortality among those below 1 year only was 186. Knowing that the incidence of tetanus infection is higher among men, especially among construction workers, why were they not included in the program?

3.) Other important questions brought up were these vaccines not submitted for testing and approval by BFAD as provided by Philippine law? Where did these vaccines come from? Countries and biological companies?

4.) What was the rationale why the standard method which has been implemented since 1980 with good results was changed in 1993? -- i.e. series of 2 injections for pregnant women not properly immunized as against the 5 serial injections in the NID program.

With existing immunization programs of the DOH, the incidence of tetanus and tetanus neonatorum has steadily declined, in fact between 1975 to 1991 tetanus neonatorum was not among the top ten causes of morbidity and mortality in the country. Even at the reported number of 318 in 1992 and the 343 cases in 1993 -- the sudden increase claimed to be due to sentinel surveillance -- the massive drive to vaccinate ALL women aged 14-44 nationwide was difficult to understand. Certainly the high risk groups and areas can be readily identified.

5.) ON THE ASPECT OF EXPENSES FOR THE VACCINATION PROGRAM -- We were told that the vaccine cost P 2.00 per patient (excluding the cost of the needle and the syringe); so if we project that to the repeatedly announced target number figured to be 3 to 7 million WOMEN, the total cost for the first injection would be between P 6 to P 14 million for the first shot and P 15 to P 35 million if ALL the 5 shots were given! Considering the scarce resources of the DOH, this amount could well be used in the prevention and control of more prevalent infectious diseases e.g. pneumonia, tuberculosis, diarrhea, which remains high in the list of the top ten causes of mortality not only among infants but in all age groups.

THE BIOETHICAL ISSUES RAISED THEREFORE TOUCHED TWO POINTS: the proper allocation of scarce resources and

responsibility of the government to assist patients who developed "unusual reactions" to the vaccine. It is the ethical responsibility of the DOH to take note of all reported adverse effects which calls for the re-evaluation of the program.

These concerns were again discussed in a second meeting of the PMA committee representatives with the UNICEF representatives Dr. Wilfredo Varona, Project Officer and Dr. Terrel Hill, Senior Health Adviser of the UNICEF Headquarters in New York. These two gentlemen acknowledged our concerns regarding the controversy.

From the above data therefore ANYONE can clearly conclude that THERE WAS NO "IRREPARABLE DAMAGE" TO THE TETANUS VACCINATION PROGRAM. And we would like to assure Dr. Maria Vilma Gonzaga that she should not feel guilty about causing any increase in incidence of tetanus because the incidence has been low in the first place. In fact we would like to thank her and many others who had the courage to bring to the attention of the health care workers serious concern about the program which gave us the opportunity to study the issues scientifically and came up with the above resolutions.

OUTCOME OF THE INQUIRY:

The anti-tetanus immunization program is now brought back to the previous universally practiced mode of immunization. According to Dr. Manolet Dayrit, DOH Assistant Secretary and epidemiologist, the tetanus shots will be given only to women who have not received any dose at all and it will NOT be given to women with pregnancy less than five months, as well as to single girls. He further added "Let us remember that immunization is not the only preventive measure for neonatal disease. A sterile environment is very important." The DOH program on training "hilots" (TBAs or traditional birth midwives) and providing them delivery kits has minimized and will continue to lessen the incidence of tetanus neonatorum.

They have also agreed that ALL vaccines MUST be tested and ap-proved by the BFAD as provided by law.

ON THE QUESTION OF PORNOGRAPHIC MATERIALS BEING USED FOR "SEX EDUCATION" AND AIDS AWARENESS PROGRAM -- Please note that there is a proliferation of these materials worldwide especially in thriving democracies -- therefore concerned groups involving parents, educators, psychologists, etc. have banded together to increase the awareness of people about detrimental effects of these materials on the young and the citizenry in general. In the United States, at the forefront of this are groups

like Morality in Media, New York, Christian Film and TV Commission, Focus on the Family, and Human Life International, (all ecumenical organizations) to name a few. There are groups in our country who have dovetailed their efforts with these organizations and these are the groups who have brought to the attention of the Church these materials in question which were found to be highly inappropriate for the so-called "Sex Education" modules (which are basically value-free). Similar programs being used in developed countries have been found to have caused untold miseries and deterioration of moral values rather than the development of wholesome attitudes on human sexuality. (Please review enclosed materials). We are also furnishing you data and research works attesting to the fact that the condom only delays but DOES NOT completely protect anyone from contracting HIV infection especially among high risk groups. Experience from developed countries also shows that actively promoting it condones promiscuity and therefore increases rather than decreases the incidence of HIV infection.

WE have also enclosed a copy of our letter of concern regarding the content of DECS POP ED modules now being used at the NCR for your perusal.

As one of the most responsible and respected journalists in the country, we hope you will be one with us in disseminating the truth and unbiased information about sensitive issues affecting not only this generation of Filipinos, but most of all the generations to come!

Thank you for your kind attention and consideration.

Sincerely yours,

ANGELITA MIGUEL-AGUIRRE, M.D.
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