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Joseph Bonnici

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Safety Issues Concerning Anti-hCG Vaccines

by

Joseph Bonnici, Ph.D.

The author is Associate Professor, Koffler Center, Bryant College, Smithfield, RI.

Introduction

Under the pretext of promoting "safe pregnancy termination services"¹ the World Health Organization (WHO) is currently supporting a massive research program for a vaccine which eliminates the human chorionic gonadotropin (hCG) hormone in the maternal endocrine system. The demise of this placental glycoprotein hormone annihilates the human blastocyst in its early life in the mother's womb without "the maternal recognition of pregnancy."^{2,3} A major premise behind this vaccine is that its users will not discover its full mode of action. "Maternal recognition" would be a setback to its potential global market given that the anti-hCG vaccine provokes antibodies resulting in an abortifacient mechanism.^{2,4} If this vaccine would eventually materialize, one may assume that its marketing campaign would likely pay lip service to its users, promoting, as the WHO's Fathalla would see it, "A reproductive rights and health approach, with women at its center."¹

Safety

It was with women at the "center" and at the expense of the "unwanted" blastocyst that the WHO task Force on Birth Control Vaccines first attempted to create a specific vaccine which would target hCG without interfering with other related glycoprotein hormones such as thyrotropin, follitropin and lutropin. Given that all these hormones share a common α -subunit, the task force focused its attention on the β -subunit where the hCG includes a unique C-terminal peptide. The basic assumption was that a specific vaccine addressing the carboxy-terminal portion of the hCG hormone (hCGBCTP) would eliminate the possibility of cross-reaction with the human luteinizing hormone (hLH).⁴ However, all this came down in 1993 to the following statement:

Although it is possible to generate specific monoclonal and polyclonal antibodies for hCG by using hCGBCTP as an immunogen, it appear[s] that the biological response to hCG [is] not affected by such antibodies. The reason for this is that the hCG-antibody complex is still able to bind to target cell receptors and therefore the intended contraceptive effect should not occur. In addition there is a risk of hazardous possible side effects such as autoimmune reaction against the ovary because . . . at least one epitope is still accessible for antibody binding on receptor-bound hCG.⁵

As Roberge explained in an earlier issue of *Linacre Quarterly*, if such side effects materialize, the vaccine user could experience premature menopause as well as osteoporosis and cardiovascular problems.⁶

Thus, while the WHO hCG-specific hCGBCTP target antigen avoids the immunological crossreactivity of hLHB and hCGB arising out of previous hCG-based research, it lacks immunological efficacy and raises safety questions.⁷ Such problems, along with Vaitukaitis et al.'s⁸ earlier writings, may shift the research attention further away to the dimer oLHa/hCGB; yet, the commonality of certain α -epitopes present in the four hormones thyrotrophin, chorionic gonadotropin, lutropin and follitropin as well as the ovine luteinizing hormone alpha, ^{9,10} along with studies about murine antibodies, ^{10,11,12} result in another warning from Dirnhofer, Wick and Berger about "the long-term safety of this type of vaccine, since it might cause autoimmune reactions and endocrine disturbances involving the gonads and the pituitary, such as secondary hypothyroidism."⁷

Hurdles

Despite such recent scientific concern, promoters of anti-hCG vaccines may seek to dispel the warnings by insisting that anti-hCG vaccines contain a pregnancy-specific antigen which is both *safe* and *reversible*. Such a statement is untenable under close scrutiny. Recent studies report a low hCG presence in non-pregnant women,^{13,14} thus dispelling the myth endorsed by the WHO in promoting its hCG research as a "pregnancy-specific" antigen. These studies also raise as-yet-unanswered questions about the importance of low hCG levels in non-pregnant women, which levels would be threatened by the vaccines.⁷ The phase I clinical trials not only failed to address long-term safety concerns;² they also contained minimal information about individual cases despite the fact that individual cases are of paramount importance for such types of vaccines.⁵

As to the reversibility issue, this can best be addressed as a long-term concern best espoused by a parallel case concerning previous medical opinion that the IUD was a reversible method. Yet, in 1995, a meta-analysis study¹⁵ showed that past IUD use could increase the risk of ectopic pregnancy. Events in the IUD trade suggest that the safety hurdles for anti-hCG vaccines can be eventually overcome through a similar variety of unethical tactics employed in the marketing of IUDs. For example, over one-fourth of IUD insertions violate medical guidelines, being inserted in patients with relative contraindications.¹⁶ Also there is evidence that some international IUD manufacturers withhold critical information in their information guidelines.¹⁷ In the United States,

women fitted with the ParaGard T380A IUD and the Progestasert IUD are asked to sign lengthy contracts (11 pages each)^{18,19} which absolve the manufacturers from a plethora of adverse reactions. If the WHO is to live up to its name, it should step in and enforce proper accountability rather than let women suffer at their own expense from widespread misconduct.

Conclusion

In Lei, Toth and Rao's study, the human fallopian tubes of non-pregnant women immunostained for hCG,¹⁴ further confirming Madersbacher et al.'s discovery of hCG in sera of healthy non-pregnant women. Thus, given that the anti-hCG vaccine is not a pregnancy-specific antigen as was originally claimed by the sponsors and given the serious health questions surrounding its use, the World Health Organization should re-examine its fixation with the vaccine. In the words of Fathalla, "Demographic concerns of the past few decades, serious as they are, should not override the human rights and health rationale of contraception." In spite of such words of caution, it increasingly seems that the research about this vaccine is being done with hCG, and not "with women[,] at its center."

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