# AN INVITATION TO JOIN AN IMPORTANT PREGNANCY-RELATED REGISTRY

#### WHAT YOU NEED TO KNOW IF YOU RECEIVED THE ANTHRAX VACCINE WHILE PREGNANT

The first thing you need to know if you received the anthrax vaccine while pregnant is that the safety of the vaccine among pregnant women and nursing mothers is not well established. Does this mean that either you or your pregnancy are at risk? No. However, it does mean that while reproductive studies in animals have not identified any harmful effects on pregnancy outcomes, the findings from what little human research has been done to date cannot yet clearly define any possible risks.

The second thing you need to know if you received the anthrax vaccine while pregnant is that you are eligible and invited to join the BioThrax (Anthrax) Vaccine in Pregnancy Registry.

### What is the BioThrax (Anthrax) Vaccine in Pregnancy Registry?

In 2008, Emergent BioSolutions, the manufacturer of the BioThrax® (anthrax) vaccine, changed the vaccine schedule and route of administration. In light of these changes, and because inadvertent vaccination of pregnant women may occur, the FDA required the establishment of a registry to monitor any potential risks to pregnancy. The DoD, with funding from the vaccine manufacturer, Emergent BioSolutions, has developed the BioThrax® (Anthrax) Vaccine in Pregnancy Registry (Registry) to track such cases.

# Why would I want to join the Registry?

You do not receive any money or additional health benefits for joining the Registry, so why join? Joining this Registry is something you can do to help others. For the foreseeable future, service members will continue to receive the anthrax vaccine. This means that a number of female service members may, like you, receive the anthrax vaccine before they realize that they are pregnant. Right now you may feel uneasy because you received the vaccine and no one knows for sure what this means for you or your pregnancy. By joining this Registry you can help us answer this question so that future female service members do not need to feel a similar unease.

## I may want to join the Registry, or at least ask some questions about it. What should I do?

Your healthcare provider may have already submitted a BioThrax® (Anthrax) Vaccine in Pregnancy Registry Referral Form (Form) for you, in which case, a Registry Team member will contact you soon. If you are uncertain if your healthcare provider submitted a Form for you, you can contact the Registry Team using the contact information below. A Registry Team member can confirm if a Form was received from your healthcare provider, determine your eligibility, and obtain your consent to join the Registry. The consent form details what data will be collected and what participation entails.

For more information regarding receipt of the anthrax vaccine in pregnancy, please visit the Military Vaccine Agency (MILVAX) website at <a href="https://www.vaccines.mil">www.vaccines.mil</a>.

For questions about the Registry, please use the following contact information:

BioThrax® (Anthrax) Vaccine in Pregnancy Registry (619)553-9255, DSN 553-9255, Fax (619)767-4806 email: <a href="mailto:nhrc-VaccineRegistry@med.navy.mil">nhrc-VaccineRegistry@med.navy.mil</a>