

**Senate Foreign Affairs, Defence and Trade
References Committee**

SUBMISSION COVER SHEET

Inquiry Title: Defence Health Arrangements Prior to Deployment

Submission No: 07

Date Received: 04.12.03

Organisation:

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Date Authorised:

SENATE REFERENCES COMMITTEE SUBMISSION – 4 DEC 03

For action by: As soon as practicable.

USE OF OUT OF DATE ANTHRAX VACCINE ADSORBED IN OPERATION GOLD (OP GOLD)



RECOMMENDATION

It is recommended that the Senate Foreign Affairs, Defence and Trade References Committee:

- **note** the contents of this submission; and
- **conduct to conclusion & publish** investigations into the use of the out of date ANTHRAX VACCINE ADSORBED for Australian Defence Force (ADF) domestic deployment in support of the Sydney 2000 Olympic Games, namely OPERATION GOLD (OP GOLD); and
- **ensure** that all ADF members who were vaccinated with out of date ANTHRAX VACCINE ADSORBED have their service for which they were vaccinated be classified as eligible service under the provisions of the VETERANS' ENTITLEMENTS ACT 1986 **and** receive proactive Commonwealth assistance for the submission of their claims for compensation which shall result in the awarding of appropriately prodigious compensation; and
- **compel** the ADF to ensure that the use of out of date vaccines is explicitly prohibited and that all staff fully adhere to such prohibitions.

OVERVIEW

- In 1993 Sydney won the right to host the 2000 Olympic Games. The ADF was called upon to support the games. As an Army Officer with a BSc, I volunteered for service with the Joint Incident Response Unit (JIRU) for OP GOLD. I was told that I had to be vaccinated against Anthrax. Prior to receiving the vaccinations I was not told that the vaccine contained a suspected carcinogen, nor that it was out of date, nor that there were over 150 adverse reactions already recorded in USA for this lot, nor that the cold chain of custody was not broken, nor that the range of adverse reactions was extensive & debilitating as I have experienced. However I was told that the vaccine would not cause cancer nor would it affect my offspring. I had the first two of six dose of the vaccine, both of which were from the same batch & out of date. Subsequently I had a severe adverse reaction which has resulted in permanent impairment which I have been told will only degenerate. I have since discovered that no studies have been performed to ascertain carcinogenic, mutagenic or fertility impairment actions of ANTHRAX VACCINE ADSORBED.
- The vaccine agent in question is ANTHRAX VACCINE ADSORBED. It was manufactured by MICHIGAN BIOLOGIC PRODUCTS INSTITUTE of Lansing, Michigan USA 48909 under U.S. licence No 99. The lot is FAV043. The expiry date is 12 Mar 00. It is supplied in a 5 ml vial containing 10 doses per vial. The NATO Stock Number (NSN), as allocated by the ADF, is 6505-66-128-7533.

SIGNED

Major Brett N. Laboo
210 Antill St
HACKETT ACT 2602

NOTED

Senator Sandy Macdonald
Chair

Tel: (02) 6257 8257

4 Dec 03

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SENATE REFERENCES COMMITTEE SUBMISSION – 4 DEC 03

For action by: No critical deadline.

USE OF OUT OF DATE ANTHRAX VACCINE ADSORBED IN OPERATION GOLD – OFFER OF ASSISTANCE

RECOMMENDATION

It is recommended that the Senate Foreign Affairs, Defence and Trade References Committee **note** that in regard to the matters detailed in my submission on the use of the out of date ANTHRAX VACCINE ADSORBED for Australian Defence Force (ADF) domestic deployment in support of the Sydney 2000 Olympic Games, namely OPERATION GOLD:

- I am willing to assist with and if necessary direct any further investigations into those matters at the discretion and pleasure of Committee.
- I am willing to appear before the committee and provide further information or clarification either publicly or in camera.

OVERVIEW

- I have been collecting information on the anthrax vaccine issue ever since I was vaccinated without my informed consent in Mar 2000 by the ADF with out of date ANTHRAX VACCINE ADSORBED.
- Some of the information that I have is potentially damaging to the ADF.
- I previously addressed this issue, i.e. the use of the out of date ANTHRAX VACCINE ADSORBED for ADF domestic deployment in support of the Sydney 2000 Olympic Games, namely OPERATION GOLD, directly, but only very briefly with Senator Bartlett by telephone in early Feb 03.

DISCLOSURE OF INTERESTS

- I have no interests in any biomedical or pharmaceutical organisations.
- I have no interest in maintaining the status quo in regard to the administration of vaccines in the ADF.
- I now have a permanent interest in exposing the whole truth surrounding the use/misuse of vaccines in the ADF.
- I have a prospective interest in the successful resolution of a claim for compensation which I am yet to submit.

SIGNED



Brett N. Laboo
210 Antill St
HACKETT ACT 2602

NOTED

Senator Sandy Macdonald
Chair

Tel: (02) 6257 8257

4 Dec 03

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SEQUENCE OF EVENTS / "FACTS"

1. In 1993 Sydney won the right to host the 2000 Olympic Games.
2. Date unknown: The ADF was called upon to support the games.
3. Mid to late 1999: An officer (LT J. King) from my unit at the time (2nd Field Hospital) was seconded to JIRU. She reported back to me that the staff at JIRU were seeking other Army Officers with science degrees in chemistry to work with the staff from Defence Science and Technology Organisation (DSTO).
4. Late 1999: After speaking with my Commanding Officer (CO), I volunteered for service with JIRU for OP GOLD and undertook some specialised lead-up training. I was then posted to 2nd/14th Light Horse Regiment (Queensland Mounted Infantry) with effect from Jan 2000.
5. Early 2000: I received approval from my new CO to continue with my plan for attachment to JIRU.
6. Early 2000: I was told by an officer from JIRU (CAPT Zimmerman) that I had to be vaccinated against Anthrax.
7. Early 2000: I expressed a mild degree of concern about having to be vaccinated against Anthrax to my CO and all that I can recall him saying is something like "Better you than me" & "Haven't there been a lot of problems with that vaccine?" I then arranged for and had a comprehensive individual medical examination to establish my degree of health & fitness prior to the vaccination, just in case there was any truth to his rhetorical question about the vaccine's alleged safety. I was assessed as being medically fit - class 1.
8. 17 Mar 2000: I attended a vaccination parade with about 30 other soldiers at the Regimental Aid Post (RAP) of the 2nd Combat Engineer Regiment (2 CER) at Gallipoli Barracks, Enoggera. 2CER was re-organised into JIRU for OP GOLD. At the vaccination parade there was an Army Medical officer who had just flown up to Brisbane from Sydney in order to conduct this vaccination parade for the JIRU personnel who had not yet deployed to Sydney. At the vaccination parade I recall that the medical officer did not tell us that the vaccine contained a suspected carcinogen (formaldehyde), nor that it was out of date, nor that there were over 150 adverse reactions already recorded in USA for this lot, nor that the cold chain of custody was not broken, nor that the anthrax vaccine is not registered for use in Australia by the Therapeutic Goods Authority, nor that the range of adverse reactions was as extensive and debilitating as I have experienced. However I was told that the vaccine would not cause cancer nor would it affect my offspring. Of note I recall one of the soldiers asking the medical officer a question that was something along the lines of "If I have this shot, will I then make mutant taddies and therefore have mutant kids?" After the short burst of nervous laughter & friendly jibing about the soldier already being a "mutant" from his peers, the medical officer answered that it was safe and there was nothing like that to be concerned about in regard to this vaccine. A little while after this the briefing concluded and the soldiers were directed to form an orderly queue in the RAP waiting room until individually called to the treatment rooms for the injection of the vaccine by the army medical staff. I then asked the medical officer if he was going to give all the soldiers a signed form as per the current instructions at the time, stating that they had all been thoroughly briefed about the risks and benefits of having the anthrax vaccine. He replied that the form in question was no longer in use and need not be completed. I also asked the medical officer how he brought the vaccine to Brisbane with him. All that I can recall is that he mentioned something about bringing the vaccine in a small styrafoam esky. To this day I have no idea how he ensured that the vaccine was kept between 2°C and 8°C for the journey. After I had my first dose of the vaccine in the upper right arm I asked the army medical assistant if I may have to keep both the box that the vaccine vial was in and package insert. It was at that time that I realised that the vaccine was out of date, so I asked the army medical assistant about it & I recall her saying something like "Don't worry about it Sir, its alright." At no time during the entire vaccination parade did I observe the medical officer write a script for each vaccination. After attending to some other minor duties & tasks I went home. Whilst at home that night & over the next few days the injection site went very red & became particularly swollen & tender, in fact too tender to sleep on it for about a week.
9. 18-30 Mar 2000: During this period I had a couple of transient/short term mild ear infections.
10. 31 Mar 2000: I attended the 2CER RAP again for my next dose of the anthrax vaccination. This time I was the only person there to be vaccinated. The army corporal medical assistant directed me to the treatment room where he then took out a preloaded syringe from the travel fridge & injected the contents to my upper left arm. It was only after he had done so, that I asked him what was the lot number. He

replied that it was the same one a couple of weeks ago, he was directed to draw up a few syringes & keep them in the fridge in order to administer the second dose to those staff still in Brisbane. Apparently the medical officer had taken the remainder of the vials back to Sydney with him, nearly two weeks prior. I then asked the soldier if he had a needle prepared for the event that someone had an immediate and severe adverse reaction. He said, yes he did, it was in the fridge. That night at home, the new injection site, on my upper left arm became more swollen tender and red than the first. Additionally I began to sneeze a lot & develop some respiratory "blockages".

- 11.1 Apr 2000: I attended my morning parade at my own unit and was preparing to participate in the physical training for that day which was a 5 to 10 km route march with full load carrying equipment. When the RAP Sergeant from my unit's RAP, who was participating in the training too, saw me he directed that I don't have any more anthrax vaccinations & that I go straight home for the day as I was coughing and sneezing so much and my eyes were watering profusely.
- 12.2 – 4 Apr 2000: During the entire weekend I coughed and sneezed so continuously and so violently that I had injured my lower back to such an extent that I was unable to even stand straight up on Monday morning 5 Apr 2000.
- 13.5 Apr 2000: I attended the RAP & the doctor prescribed me some vallium & some anti- inflammatories. I was also given some time off work in order to recuperate.
14. Mid 2000: I still had residual back pain & was referred for a scan of my back. It was revealed that I had in fact ruptured my L4/L5 intervertebral disk. This injury has since curtailed my activities and life style very considerably.
15. 2000-03: I have been medically downgraded specifically due to the injury to my back which I believe resulted from an adverse reaction to an out of date vaccine which I was told was safe yet there were no studies done to support those claims. Additionally I have been suffering from chronic recurring viral ear infections. And protracted malaise & lassitude but of apparently unknown origin, yet they are listed as characteristic of systemic adverse reactions to the vaccine.
16. 2003: In hindsight, had I known that the vaccine contained a suspected human carcinogen, was not tested for carcinogenic action and was out of date (i.e. I was fully informed of the medical procedure that I was about to under go) it is very likely that I would have not had the vaccine at all. However the ADF denied me (and about 30 other soldiers) this basic right and now I am (and possibly we are) suffering as a result.

EVIDENCE

In support of the above, I am able to provide physical evidence which establishes the bulk of what is stated. Should the committee require this from me then I am prepared to release certified copies only, as I am keen to retain personal custody of the original documents.

There are a number of issues for which I have no evidence but it is requested that the committee seek these from the ADF. In particular I draw the committee's attention to the following:

Given that there was about six years lead time for the military preparation for OP GOLD, why was an out of date anthrax vaccine used?

At the time of the vaccinations in question, what was the official policy for the use of or extension of potency periods for out of date vaccines?

Who is responsible for the testing of pharmaceutical items in order to determine and/or grant extensions of potency periods?

What records are kept in relation to these extended potency periods?

For the members who are treated with pharmaceutical items that have been granted extensions of potency periods, what information are they told?

If there was a policy, to what extent was it followed & was ANTHRAX VACCINE ADSORBED Lot FAV043 tested prior to its expiry date by the ADF and granted an extended potency period?

Does the testing procedure to determine and/or grant extensions of potency periods take into consideration previous adverse reactions to the pharmaceuticals in question?

At the time of the vaccinations in question, were all the medical trades in the Army explicitly taught to discard pharmaceuticals that had elapsed expiry dates?

Who are the other soldiers who were vaccinated with the same out of date anthrax vaccine as me?

What are all of the adverse effects that they have suffered/experienced if any?

Given that the vaccine we received was past the expiry date, why weren't we told that there were over 150 adverse reactions recorded for that particular lot?

For every person who has been ever been vaccinated by the ADF with the ANTHRAX VACCINE ADSORBED, how many of them were told:

that it contains a suspected human carcinogen yet the vaccine has not been studied to determine any carcinogenic action?

that it has not been studied to determine any effect on fertility?

that the vaccine is not licensed for use in Australia by the Therapeutic Goods Authority (TGA)?

Why did the three service newspapers run front page stories in Feb 03 claiming that the anthrax vaccine was safe yet according to the package insert from the manufacturer no studies had been performed to determine any carcinogenic action nor effect on fertility?

If every person who has ever been vaccinated by the ADF with the ANTHRAX VACCINE ADSORBED hasn't been told about the lack of proven safety as per the package insert from the manufacturer, then what recourse do they have in regard to any possible future claims for compensation?

By what authority does the ADF use pharmaceuticals that are not licensed for use in Australia by the TGA?

Does the ADF accept at face value, i.e. offer no challenge to the contrary, the claims made in the package insert for ANTHRAX VACCINE ADSORBED from the manufacturer?

On what grounds is it ethically sound to tell patients that a certain pharmaceutical item which they are about to be treated with is safe when it hasn't been proven?

At the time of the vaccinations in question what was the ADF policy for the guarantee of cold chain of custody for pharmaceutical items requiring temperature controlled storage and transport?

How was this policy followed in practice?

Are there any other cases of either suspected or actual breaches of the cold chain of custody for anthrax vaccines which have subsequently been injected into ADF patients?

If there were adverse reactions to these injections to what extent are those patients eligible to claim for compensation?

How are these patients able to demonstrate that the cold chain of custody was breached or not?

What was the ADF policy at the time of the vaccinations in question, for the writing of medical prescriptions for the injection of vaccines & has this changed since then?

What was the ADF policy at the time of the vaccinations in question, for the recording of vaccines injected to patients & has this changed since then?

To what extent were these policies followed for the vaccinations and patients in question?

DESIRED OUTCOME

My desired outcome of the results of any inquiry into the matters herein mentioned is as follows:

- honest & unbiased provision of information in real-time.
- acknowledgment by the ADF of my condition and the factors surrounding / leading to it.
- a non-intrusive Senate oversight of any resulting compensation claims.
- full assurance that what has happened to me and the other soldiers, in relation to the use of an untested out of date vaccine will not occur ever again and that the briefing information given to all prospective vaccination patients includes at least all of the information in the manufacturer's package information.

OTHER POTENTIAL OPTIONS OPEN FOR RESOLUTION OF THIS ISSUE

- ADF Health Care Complaint – I do not believe that this issue would have been dealt with in an unbiased manner, as there is a conflict of interest in that the medical profession seems to want the public to keep their faith in vaccines as being all that is claimed, thus will not fully explore or will even actively ignore claims to contrary.
- ADF/Army Chain of Command – Once again I do not have faith in this approach to satisfactorily deal with the issue because there are careers involved and these people do not want to jeopardise their livelihood over such a controversial issue. In fact back in Feb this year, after I told my superior officer that I had spoken to Senator Bartlett about the use of the out of date ANTHRAX VACCINE ADSORBED for Australian Defence Force (ADF) domestic deployment in support of the Sydney 2000 Olympic Games, namely OP GOLD, he phoned his superior officers, directed me to write out a record of conversation and not to speak with Senator Bartlett again on the issue. (I now consider this to be unlawful, thus due no obedience.) Now, when I was speaking with Senator Bartlett I thought that I was in effect giving an in camera verbal submission to the committee on which he was then a member of and was therefore entitled to the normal protections afforded. I subsequently heard that as a direct result of my speaking with Senator Bartlett, a hot issues brief was prepared for the Chief of the Defence Force who was at the time before the committee discussing the issue of Royal Australian Navy personnel who had refused the anthrax vaccine and related issues. Additionally, a subsequent telephone conversation with the Director of Defence Health Service Branch did not inspire my confidence in the chain of command to effectively handle this issue.
- Defence Whistle Blower Scheme – I have not used this scheme, nor do I know anyone who has and it's efficacy is unknown.
- Redress of Grievance – I do not consider that this option has any thing to offer in way of a solution.
- Submission to Senate Foreign Affairs, Defence and Trade References Committee – I consider that this is a feasible option as there is a high degree of compliance to the directions of such committees in the Department of Defence, the committee has very extensive powers of investigation, bias is negligible, and in general once committee members identify a weakness in an organisation that has led to a failure of that organisation to deliver what is required of it, in this case, duty of care & disclosure to members undergoing medical procedures in preparation for military operations, then the committee is exceptionally diligent in pursuing the issue through to its entire completion.

DISCLOSURE OF INTERESTS

- I have no interests in any biomedical or pharmaceutical organisations.
- I have no interest in maintaining the status quo in regard to the administration of vaccines in the ADF.
- I now have a permanent interest in exposing the whole truth surrounding the use/misuse of vaccines in the ADF.
- I have a prospective interest in the successful resolution of a claim for compensation which I am yet to submit.

CONCLUSION

In conclusion, I wish to state that I make this submission to the committee completely void of all malicious intent and with desire to see the truth revealed objectively and other service personnel protected from what I have experienced. Additionally I have not knowingly made any false statements but acknowledge that I am fallible and have attempted to the best of my recollection present the truth as I know it.

"A difficult truth is better than a small lie"