THE POISON VACCINE

HOW THE HEALTH OF HUNDREDS OF AMERICAN SOLDIERS WAS SERIOUSLY DAMAGED AFTER ANTHRAX INOCULATION

November 26, 2002 The Times 2 - features (PAGE 1)

Ronda Wilson was once fit and healthy. Now her body has been ravaged by the effects of the anthrax jab

(PAGES 4-6)

THE NEEDLE AND THE DAMAGE DONE

HUNDREDS OF AMERICAN SOLDIERS HAVE SUFFERED SERIOUS ILLNESS AFTER BEING COMPULSORY INJECTED WITH A CONTROVERSIAL ANTHRAX VACCINE, A BATCH OF WHICH HAS BEEN FOUND TO BE CONTAMINATED. TIM REID**INVESTIGATES**

Hundreds of American soldiers have suffered serious illness after being compulsorily injected with a controversial Anthrax vaccine, a batch of which has been found to be contaminated

ON THE MORNING of December 17, 1998, Ronda Wilson, a supremely fit, strikingly beautiful American helicopter gunship pilot, was heading for military stardom. Just 21 and the only woman in her squadron, she had recently defeated her 63 male fellow pilots to earn the coveted Top Gun award in her first gunnery flight test. She was without peer in her cavalry unit, so skilled at handling the OH-58 Delta Warrior, armed with Hellfire missiles and .50-calibre machine guns, that she was described by her commanding officer as "one of the most outstanding pilots of her generation".

On that morning, at Fort Stewart, Georgia, she received a routine order that was ultimately to destroy her faith in the military family and American government which she loved beyond question, and which she says "I was willing to die for". She was told to "go get your jabs".

She was never told what the injection was for, and felt no need to ask. It was, she later discovered, the first in a six-dose course of anthrax vaccination. It was the moment she became part of the US government's compulsory, highly ambitious anthrax vaccination programme for all 2.4 million of its military personnel; the project was authorised by President Clinton himself, it had begun eight months before, and it was halted 18 months later amid damning congressional verdicts, lawsuits and accusations of a top-level cover-up.

There were many things Wilson was not told about the 0.5ml phial of milky liquid that was being injected into her arm. It was manufactured by a company that today, after a new lease of life for the vaccination programme, has begun to distribute millions of doses to immunise "high-risk" US troops heading to the Persian Gulf for an attack on Iraq. (British soldiers will not be immunised with this vaccine, but with a home-grown version, produced at Porton Down).

Critics of the vaccine, who include congressmen, senior military officers and more than 450 American servicemen who have been court-martialled or forced to leave the military for refusing to take it, say its ability to combat inhalation anthrax has never been proven and it has never been tested on humans; it has never been licensed to combat inhalation anthrax; and its long term effects have never been known. Those claims are supported by a congressional committee which issued a scathing and alarming report into the efficacy and supervision of the vaccine, and the immunisation programme, in April 2000.

Its critics also claim it is being forced on the country's soldiers as part of a politically-inspired attempt to persuade the American public that an effective vaccine against an anthrax terror attack exists, and that its soldiers are safe from Saddam Hussein's chemical and biological arsenal.

The Pentagon, and BioPort, the manufacturer, together with the Food and Drug Administration, which licenses US drugs, fiercely deny these claims. *The Times* has looked at thousands of pages of government, FDA, Army, congressional and medical reports stretching back 30 years. The extraordinary story of this anthrax vaccine, suddenly thrust on to centre stage in a new age of global terror, is one of high-level politics, furious scientific dispute, big business and great controversy.

One thing is certain — this vaccine has a history. Questions persist on two levels: the ability of the company that manufactures it to produce it safely, and the safety and effectiveness of the vaccine itself. There is testimony and documentation that raise the question of why the American military establishment and successive White House administrations have persisted with a company and a vaccine that by their own admission have suffered problems. It is a history that the hundreds of thousands of US troops about to receive the compulsory immunisation, and who have no right to refuse it, are not being told about.

Of all the things Wilson was not told about her first jab, perhaps the most crucial was this: that 10 months earlier, in February 1998, after an inspection of the Michigan laboratory that manufactures the vaccine, the plant had its authority to make the vaccine suspended by the FDA.

The inspection followed five years of warning letters citing concerns over the plant's record-keeping and violations in safety, potency consistency and sterility. The February 1998 FDA report, which effectively prevented the plant from manufacturing fresh supplies of the vaccine for three years, and a copy of which has been obtained by *The Times,* is damning.

The 95-page report found lots of the vaccine contaminated, a filtration process not authorised by the FDA, problems with cleanliness and the sterility of equipment and a failure to ensure a uniform potency of the drug.

"The firm routinely redates Anthrax Vaccine lots that have reached their labelled expiration date," the report says. And it states: "Lot FAV036 was at room temperature for 20 hours, the filling operation was aborted, it was placed back in the refrigerator." According to military records it was a dose from Lot FAV036 that was given to Wilson that December morning, eight months after the FDA report had been sent to BioPort.

“The patient reported no significant reactions with the first shot,” her final military medical report states — written in April 2001 when a depressed, emaciated and mentally confused Wilson was discharged from her unit — “except for an immediate large painful local reaction at the injection site (described as being slightly smaller than a golf ball). The pain extended from her shoulder to her elbow. The military medical community reassured her this was normal. She also reported the onset of about three headaches a week.”

After her second jab, from a different lot, in January 1999, she developed “irritability, loss of memory, fatigue. By late February to early March nausea and diarrhoea started. One week after her third anthrax vaccine dose her gastro-intestinal symptoms worsened further, evolving into her current disabling state of illness.”

That current state is pitiful. Wilson, who four years ago was in superb health and in charge of one of the most potent weapons in the US armoury, can barely drive a car. She has lost a third of her body weight and suffers such agonising cramps every day that she is forced to curl up in a foetal position for hours at a time. She has stiff joints, chronic fatigue, anaemia, difficulty with simple sums, memory loss, blackouts, permanent abdominal pain and, according to her medical report, “loss of cognitive function”.

She is sure the anthrax jabs caused her physical and mental degeneration, but understands the difficulty in proving it. The final medical report concluded: “There were no other risk factors present . . . that could account for her symptoms. The anthrax vaccination may have adversely affected her immunological balance. There is a clear temporal association with the onset of her illness and her anthrax vaccination. While it is not possible to scientifically prove causality between anthrax vaccination and the onset of her illness, it is impossible to disprove causality.”

Wilson understands those problems of proof. What has destroyed her trust in everything she once held dear — the US military, the US government and her husband, a fellow pilot who has now left her — is that for 18 months she was led to believe she was a freak, the only soldier to have become ill after the injections, a strange one-off. Military doctors would diagnose stress, Aids, leukaemia, anything except a possible link to the vaccination. And, she says, as soon as she became ill, “they couldn’t wait to get rid of me”.

But in the summer of 2000, at the Walter Reed Army Medical Centre in Washington DC, she met another soldier reduced to a sad husk by, he claimed, an anthrax jab. He began to tell her what he had learnt about the vaccine, and about the hundreds of soldiers who claim it has made them chronically ill with fatigue, auto-immune diseases, severe joint pain and infertility.

It was a story that left Wilson feeling "betrayed by everything I once believed in". Sitting in her rented flat in Savannah, Georgia, and often close to tears, she asks: "How could they not tell me the history of this drug, to make me believe I was an aberration?"

Jon Irelan, a retired Army major and US Ranger, was on a tour of duty in Saudi Arabia in 1999 when he was given four anthrax jabs. Soon he was losing his hair and suffering fevers and muscular weakness, mood swings and bed-sweats. Ultimately he discovered that his testicles had shrivelled up and died. He will be on testosterone injections for the rest of his life. "Right from the beginning they refused to send me to an American medical facility," he says. ."They kept sending me to Saudi doctors. They told me it was a freak reaction. There were guys being airlifted to the Army Hospital in Germany for ingrowing toenails. I thought I was an anomaly."

In June 2000 Irelan, back in the US, contacted his congressman, Washington State's Jack Metcalfe, who sat on the House Government Reform Committee which was investigating the vaccine. "His office told me I was not alone. Then I started receiving calls from others, telling me I was not crazy. The calls have not stopped.

"I would have been happy to accept this if I had been told the problems with the vaccine. Shit happens. But they treated me like a dog."

In October 2000, Irelan gave evidence before the House committee. "Members of Congress," he said, "I appear before you today to tell you that I would willingly lay down my life for the United States of America. But what I wish someone would explain is why it has been permitted to perpetrate this unproven drug on my fellow soldiers." It was a question worth asking, because a long paper trail shows how concerned the US Government has been about the vaccine for more than 15 years.

The first anthrax vaccine was designed in the 1950s to protect wool-mill workers from cutaneous anthrax, which enters the body through breaks in the skin. In 1970 the federal government issued the only licence to manufacture a similar vaccine to the Michigan Department of Public Health. That later became the state-owned Michigan Biologic Products Institute (MBPI). That licence was based on a scientific study of an earlier vaccine which had suggested an effectiveness against inhalation anthrax. "There was a presumption of effectiveness, but it has never been tested, which is a legal requirement," says a congressional aide on the House Government Reform Committee, which had called for the immunisation programme to be suspended in April 2000.

By the late 1980s MBPI, with antiquated facilities, was making small batches of the vaccine, about 15,000 to 17,000 doses every four years, selling them mostly to people

in the animal hides business. It was the only US company making an anthrax vaccine. With the reduction in the relevance of nuclear weapons, the Cold War now over, the US Army had begun to take an interest in chemical and biological warfare. It investigated the possibility of contracting MBPI to supply the US military with the vaccine. This was before vaccinations became politically sensitive, and the Army and Pentagon statements are now a matter of public record. They are striking in their bluntness.

In 1985 a US Army report stated: "There is no vaccine in current use which will safely and effectively protect against all strains of the anthrax bacillus. A licensed vaccine against anthrax . . . is currently available for human use. The vaccine is, however, highly reactogenic, requires multiple boosters to maintain immunity and may not be protective against all strains of anthrax bacillus."

In 1989, a year after the Army had gone ahead with ordering 300,000 doses from MBPI, a letter from the Pentagon to Senator John Glenn stated: "Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunisation for a variety of reasons, a higher than desirable rate of reactogenicity, and, in some cases, lack of strong enough efficacy against infection by the aerosol route of exposure."

Then came the Gulf War. Amid claims that the vaccine may have caused the illness of thousands of troops after 150,000 were vaccinated — allegations never proved — hearings were held by the Senate Veterans Affairs Committee. In December 1994 it stated: "The efficacy of the vaccine against biological warfare is unknown."

In the 1994 medical textbook *Vaccines*, Colonel Arthur Friedlander, the US Army's chief anthrax vaccine researcher, wrote: "The current vaccine against anthrax is unsatisfactory for several reasons. The vaccine is composed of an undefined crude culture . . . the degree of purity is unknown . . . the presence of constituents that may be undesirable may account for the level of reactogenicity observed."

This is the same vaccine — the same ingredients, if not the same batch — being administered to troops today.

In October 2000, Col Friedlander gave evidence to the House committee. He said: "This vaccine is safe and effective, and it's the best vaccine we have to protect against this disease."

Col Friedlander says he has taken the vaccine himself. There is no reason to believe his assertion before the committee was not genuinely held. One thing, however, had changed: the determination of the US government to immunise the entire military.

Throughout the 1990s, MBPI had been manufacturing millions of doses in the conditions so damned by the February 1998 FDA inspection, as political demands for the vaccine grew. In 1996 the Khobar Towers bombing in Saudi Arabia killed 19 US troops. Pan-Arab terrorism had begun in earnest. The spectre of biological terrorism was becoming a genuine political concern. So the Army again looked at the anthrax vaccine. This time the plan was bold: a mass immunisation programme for all 2.4 million servicemen and women.

In 1995 the Army contracted the SAIC Corporation, consultants to the Pentagon, to submit a plan that would enable them to obtain an FDA licence for inhalation anthrax. In its report, the SAIC's plan clearly identified the vaccine's legal status: "This vaccine is not licensed for aerosol exposure expected in a biological warfare environment." Under US law, the lack of such a licence meant that soldiers could not be given the vaccine without their "informed consent", a hurdle that would have made a mass immunisation programme impossible.

On September 20, 1996, MBPI submitted an Investigational New Drug (IND) application to the FDA. Again, one of its purposes was clear: "To obtain a specific indication for inhalation anthrax." That IND application has never been acted upon by the FDA.

Six months later the FDA's stance on the vaccine appeared to change. In 1997 a new Defence Secretary, William Cohen, made combating bio-terrorism a priority. On March 4, 1997, four days after the retirement of the long-serving FDA Commissioner David Kessler, the Assistant US Defence Secretary (Health Affairs), Dr Stephen Joseph, wrote to the acting FDA Commissioner, Dr Michael Friedman. Dr Joseph said the Defence Department had "long interpreted" the vaccine as being effective for inhalation anthrax. This was six months after the IND application.

Dr Friedman replied on March 13. It was a response that seemed to clear the regulatory hurdle for a mass immunisation programme: "While there is a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax, the current package insert does not preclude the use." The insert said the vaccine was licensed for "at risk" industrial and veterinary workers. It did not specify the type of infection.

Meanwhile, MBPI was in financial trouble. In June 1998 a private consortium named BioPort, headed by a Lebanese businessman, Fuad El-Hibri, bought the company for $24 million. A major shareholder and director of BioPort was Admiral William Crowe, Chairman of the Joint Chiefs of Staff under the Reagan and Bush Senior administrations, and a friend of El-Hibri; the two met while Crowe was Ambassador to the UK.

Less than a month after the sale of MBPI, BioPort landed an exclusive $29 million contract with the Pentagon to "manufacture, test, bottle and store the anthrax vaccine." Admiral Crowe has vehemently denied that he knew of the deal before BioPort purchased MBPI. He also insists that the vaccine is safe.

Within months, BioPort too was in trouble. Unable to rectify in time the problems highlighted in the FDA's February 1998 inspection report, the new owner, like MBPI before it, was unable to ship any new vaccine. It appealed to the Pentagon for more money. By June 2000 the Anthrax Vaccine Immunisation Programme (AVIP) had all but ended, due in large part to dwindling supplies. Not until January this year was BioPort authorised to start shipping new vaccines. But between March 1998 and January 2000, according to the Pentagon's own figures, 2.1 million doses of stockpiled, pre-February 1998 vaccines were administered to 535,000 troops. Only in August did the FDA prohibit BioPort from using any pre-1998 vaccine. During that period the Pentagon spent over $100 million of taxpayers' money renovating the plant. It is also paying about $20 a dose, more than three times the original price negotiated three years ago. And critics point out that no matter how much money has been spent renovating the plant and cleaning up the manufacturing process, the vaccine itself, given to troops heading to the Gulf today, has not changed.

Six months after the FDA inspection of the plant, Captain Tom Rempfer and Major Russ Dingle, officers in the Connecticut Air National Guard, were asked by their commanding officer to look into the vaccine. Misgivings about the jabs had begun to spread, and it was felt that their investigation would put the minds of fellow pilots at rest.

It didn't. The two officers wanted to go public when they discovered the FDA inspection report. Senior officers in their unit, they say, ordered them to keep their discovery secret. They then refused to take the jab, and were ordered to resign their commissions. Both pilots have filed federal lawsuits against BioPort challenging the effectiveness of the vaccine. The sister of Sandra Larson, a soldier who died three months after her sixth jab, has also been joined by Ronda Wilson in suing BioPort. Their lawyer, Alan Milstein, says he hopes to bring a class action involving hundreds of former servicemen. Their cases, they say, have been greatly helped by the House of Representatives.

In April 2000, after days of testimony, the House Government Reform Committee released its verdict on the vaccine. It stated: "The AVIP programme . . . leaves the Department of Defence captive to old technology and a single, untested company . . . based on a dangerously narrow scientific and medical foundation. The safety of the vaccine is not being monitored adequately." As a health care effort, "the AVIP compromises the practice of medicine to achieve military objectives."

It derided the “preposterously low” adverse reaction rates reported by the Pentagon, which is “more concerned with public relations than effective force protection”. It adds: “Adverse events following vaccination are reported by women at twice the rate among men.” And it concludes: “AVIP raises an ominous question: who protects the force from ill-conceived force protection?” The House committee, chaired by Dan Burton and Christopher Shays, both Republican congressman, recommended that the AVIP programme be suspended. Lawrence Halloran, a senior aide to Shays, says: “The FDA was leant on by the Department of Defence in 1997, and took a shortcut. They interpreted the old licence on the fly, giving the vaccine approval. It is not a standard you would find anywhere else. No other drug manufacturer would be given approval for a product like this.

“The committee concluded that it is not licensed for inhalation anthrax. There is no question it is harmful to some people’s health. To persist with using this vaccine at the expense of developing a new one is a scandal.”

So how can the Pentagon be allowed to vaccinate troops with such a discredited product? “Because they can,” Halloran says. “They felt a desperate need to have something at hand, and this was already on the shelf. After the Gulf War they panicked, and felt they had to do something. They have the weight to intimidate the FDA into ignoring the problems.”

In August the FDA acknowledged problems with the vaccine. The product insert was altered dramatically. It said the vaccine could harm people with immunity disorders, could cause a host of serious long-term adverse reactions and could already be responsible for six deaths and a number of birth defects. According to the Pentagon, of the 535,000 troops inoculated, 1,578 have reported adverse reactions with 208 classified as “serious”.

The insert warnings were based in part on a report by the US General Accounting Office earlier this year, which stated that adverse reactions occur in five to 35 per cent of people who take the injection, vastly higher than a previous Pentagon claim of only 0.2 per cent. The GAO also criticised the pressure exerted on troops not to report adverse effects, so as not to jeopardise their military careers.

James Turner, a Pentagon spokesman, says: “The vaccine is safe and effective. Period.” He points to the FDA’s own evaluation of the vaccine. Kim Brennan Root, of BioPort, refers to the product insert, which states: “BioThrax is also indicated for individuals at high risk of exposure to bacillus anthracis spores.” She says: “It doesn’t say it is licensed for one type of anthrax over another. There are three types: inhalation, cutaneous and intestinal. The critics keep pointing to the 1996 IND application. They say the licence does not specify inhalation anthrax. Well, the licence

merely specifies that it protects against the disease, regardless of what form you contract. If you follow the critics' line of argument, we would have to expose people to high levels of inhalation challenge. We have monkey studies which support the effectiveness of the product for all three types."

In August the FDA gave a 25-page, point-by-point response to a Citizen's Petition filed by Major Dingle. It stated that in 1972, when the FDA assumed responsibility for regulating the drugs industry, independent panels reviewed the vaccine, concluding that it is "safe and effective". Referring to its own February 1998 inspection of BioPort, the FDA states: "Inspectional observations do not necessarily render the anthrax vaccine unsafe or ineffective."

Their assurances are of little comfort to Ronda Wilson. She says: "Everybody said I should get over my anger. But anger is the only thing that gets me out of bed in the morning. I have lost my marriage, my career, my dreams, my future, my pleasures. I would have died for my country. But I didn't think I would die like this."