## 108TH CONGRESS 1ST SESSION S. RES. 278

Expressing the sense of the Senate regarding the anthrax and smallpox vaccines.

## IN THE SENATE OF THE UNITED STATES

NOVEMBER 25, 2003

Mr. BINGAMAN submitted the following resolution; which was referred to the Committee on Armed Services

## RESOLUTION

Expressing the sense of the Senate regarding the anthrax and smallpox vaccines.

- Whereas military personnel are asked to risk and even sacrifice their lives and the well-being of their families in defense of the United States;
- Whereas vaccines are an important factor in ensuring force health protection by protecting the military personnel of the United States from both natural health threats and health threats resulting from biological weapons in overseas conflicts;
- Whereas vaccines offer significant benefits and protections that must be carefully balanced with the reality that vaccines and drugs generally carry rare but serious adverse events and life-threatening risks;

- Whereas in 2002, the insert label for the anthrax vaccine required by the Food and Drug Administration was revised to include approximately 40 serious adverse events with information that "approximately 6 percent of the reported events were listed as serious.";
- Whereas in 2002, the Food and Drug Administration also compelled the manufacturer of the anthrax vaccine to substantially revise the package insert and changed the risk to pregnant women from Category C (a possible risk) to Category D (a known risk) because of "positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans";
- Whereas in 2002, the General Accounting Office reported "an estimated 84 percent of the personnel who had had anthrax vaccine shots between September 1998 and September 2000 reported having side effects or reactions. This rate is more than double the level cited in the vaccine product insert. Further, about 24 percent of all events were classified as systemic—a level more than a hundred times higher than that estimated in the product insert at the time";
- Whereas in June 2003, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention withdrew its support for expanding the smallpox vaccination program for first-responders after finding that 1 in 500 civilians vaccinated for smallpox had a serious vaccine event;
- Whereas in 2002, the General Accounting Office found that 69 percent of experienced pilots and aircrew members in the National Guard and the Reserve reported that the anthrax shot was the major influence in their decision to

change their military status in 2000, including leaving the military entirely;

- Whereas in the war in Iraq that continues as of the date of enactment of this resolution, the British and Australian militaries have conducted voluntary anthrax vaccine programs, and other allies who have been offered the anthrax vaccine have declined;
- Whereas in March 2000, the National Institute of Allergy and Infectious Disease reported in the "Jordan Report 20th Anniversary: Accelerated Development of Vaccines 2000" that no data existed to support the effectiveness of the anthrax vaccine against pulmonary (inhalation) anthrax in humans;
- Whereas because anthrax can be prevented and treated with antibiotics and other options are either in clinical trials or development, the current anthrax vaccine is not the only choice for force health protection;
- Whereas in the 2002 State of the Union address, President Bush placed a national priority on developing a new anthrax vaccine and a newer and safer smallpox vaccine is also in development; and
- Whereas the threat of anthrax and smallpox attacks against the deployed troops of the United States has significantly diminished since the overthrow of Saddam Hussein and the disruption of Al Qaeda activity in Afghanistan: Now, therefore, be it
  - 1 Resolved, That it is the sense of the Senate that—
- 2 (1) the Secretary of Defense should reconsider
  3 the mandatory nature of the anthrax and smallpox
  4 vaccine immunization program, pending the develop-

ment of new and better vaccines that are under de velopment as of the date of enactment of this resolu tion;

4

4 (2) the Secretary of Defense and Board for
5 Correction of Military Records should reconsider ad6 verse actions already taken or intended to be taken
7 against servicemembers for refusing to accept the
8 anthrax or smallpox vaccine;

9 (3) the Secretary of Defense and the intel-10 ligence community should reevaluate the threat of 11 anthrax and smallpox attacks on troops in Iraq and 12 Afghanistan to reflect operational realities as of the 13 date of enactment of this resolution when consid-14 ering the continuation of a mandatory military vac-15 cination program; and

16 (4) the Secretary of Veterans Affairs should as17 sess those adverse events being reported with respect
18 to the anthrax and smallpox vaccines, research caus19 al relationships, and estimate a future cost to the
20 Department to treat these conditions.

0