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November 25, 2002

Dockets Management Branch HFA-305
Docket Number 02N-0466
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

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11/25/02

RE: Public Comments on proposed smallpox vaccination of young children.

To Whom It May Concern:

On behalf of the Illinois Prairie State Chiropractic Association (IPSCA) I would like to make the following remarks concerning the testing of smallpox immunizations on two to five year olds. As proponents of Chiropractic, the largest drug-free and surgery-free health profession in the USA, we are concerned for the well-being of the 40 subjects of this first study and any future kids who undergo this procedure. We feel there is no sound scientific reason to pursue this trial of the dangerous smallpox vaccine.

Our rationale for this objection starts with the complication risks (this comes from the package inserts for Dryvax from Wyeth Labs, 1960). For children ages 1-4 the death rate is 2 per million vaccinated with the same percent also having postvaccinial encephalitis, 44 per million will have severe eczema vaccinatum, 233 will have generalized vaccinia (widespread smallpox/cowpox), 577 will have accidental infection and 9600 erythematous urticarial reactions! Many researchers feel that these numbers were underreported by physicians. Dr. Robert Mendelsohn ("The People's Doctor") states in his newsletter that the risks of hospitalization after the smallpox immunization was 10 per million vaccinations and the risk of serious complications was a startling 1000 cases per million primary vaccinations. Earlier this year The American Academy of Pediatrics stated: "Based on the studies from the 1960's, 15 out of every million people vaccinated will face life-threatening reactions" (Associated Press) and the statistic would be higher for young children. Last fall 125 health workers were vaccinated at disease centers and the doctors who gave the injections were surprised by the number and severity of adverse reactions (from the National Vaccine Information Center); over 50 percent of the recipients had swollen lymph nodes and fever.

We also must consider the risk of secondary vaccinia, the live vaccine utilized has the ability to spread from those who have been "shot" to those that have not been "shot." You may be putting people in danger who are not wanting to or physically unable to take the risk of the cowpox injection. Due to the strength of this agent there are many contraindications to being vaccinated: infants failing to thrive, individuals with eczema, other skin conditions, wounds, burns; siblings or household contacts of these individuals; persons receiving x-ray, ACTH,

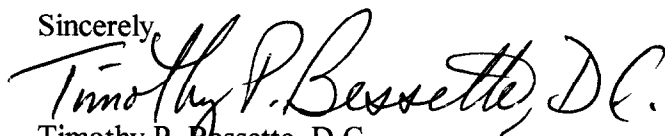
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steroids, immuno-suppressive drugs; people with immune system problems, pregnant women, those undergoing prevention or treatment of recurrent herpes, warts or *any other diseases* (emphasis added). This adds a significant number of individuals who should not be exposed to this possible smallpox secondary transfer.

Why should we risk the future health of these young children? Between the ages of two to five a child's immune system is immature, it is in the midst of developing into a fully functional coordinated systems. The sudden influx of foreign antigens via injection causes a crisis situation for the child's body and can disrupt and distort the normal antigen/antibody maturation cycle. It's postulated that past vaccination programs have resulted in long-term problems that arise later in life (e.g. the startling increase in auto-immune conditions). Finally we must consider that: "We do not yet know that the bad guys have the smallpox virus," (Ron Davis, public health expert and member of the AMA board of trustees). Please do not approve this research project. Would you like one of your children or grandchildren to be one of the subjects?

Sincerely,

A handwritten signature in black ink that reads "Timothy P. Bessette, D.C." The signature is written in a cursive style with a large, stylized initial 'T'.

Timothy P. Bessette, D.C.
IPSCA Pres.