Evaluation of Humane Endpoints for Pertussis Vaccine Safety Testing

Welcoming Remarks and Introduction

William S. Stokes, DVM, DACLAM, DACAW, BCES, RADM, U.S. Public Health Service, Executive Director, ICCVAM
Director, NICEATM
November 27, 2012
William H. Natcher Conference Center
Bethesda, MD
Animals Used for Testing by Major Categories (EU 2010)

Total EU annual animal use for testing: 2,832,000

- Production and QC of Medicines, Biologics, vaccines etc. (63% of 1,788,000)
- Toxicity Testing (37% of 1,044,000)

In 2008, the total number of animals used for experimental and other scientific purposes amounted to just over 12 million.

Use of Animals for Testing that Involves Unrelieved Pain and Distress (No Pain Relievers Used)

- 57% (54,889) of the animals reported to USDA that experience unrelieved pain and distress are used for testing Biologics and Vaccines
- Including rats, mice, and birds (not reported to USDA):
  - Est. 2 million animals used for testing that involves unrelieved pain and distress (in the U.S.)

Animals by Testing Type Reported to USDA (2010):

- Biologics and Vaccine Testing: 57% (54,889)
- Toxicity and Efficacy Testing: 38% (37,108)
- Research: 5% (5,126)

Humane Endpoints for HIST

- The most widely used (US and EU) test for absence of residual PTx activity in acellular pertussis containing vaccines is an *in vivo* test based on a lethal histamine sensitizing effect in mice (HIST).

- As an alternative to the lethal end-point assay a more sensitive histamine sensitization test based of measurement of rectal or body temperature in mice has been developed.

- Use of body temperature as an endpoint is currently approved in Japan and by the WHO.
First Presentation

Highly Sensitive Histamine-Sensitization Test for Residual Activity of Pertussis Toxin In Acellular Pertussis Vaccine Using Body Temperature Monitoring

Masaki Ochiai, PhD
National Institute of Infectious Disease, Japan
Second Presentation

In Search of a Humane Endpoint for the Histamine Sensitization Assay

Juan Arciniega, DSc,
Center for Biologics Evaluation and Research, U.S. FDA

Open Discussion