Benefits of Vaccines

- Smallpox eradicated
  - In 1900 - >20,000 cases and 1,000 deaths
- Polio eliminated
- Control or near elimination of
  - Measles
  - Mumps
  - Rubella
  - Tetanus
  - Diphtheria
  - Pertussis
  - Haemophilus influenzae type b (Hib)
Reasons for Increasing Vaccine Safety Concerns

- No vaccine is perfectly safe
- Temporal association with serious illnesses
  - Coincidental or causal
- High vaccine coverage
  - Benefits of vaccines not as obvious
Vaccine Safety Hypotheses

- Number of hypotheses linking vaccines to adverse events increasing
- Broader range of medical conditions
- Often limited scientific data
- Definitive, but divergent opinions lead to a polarized climate
The Challenge
Re: Vaccine Safety Hypotheses

- Evaluation – rapid, credible, expert
- Causality determination - likelihood based on totality of evidence and scientific information
- Prioritization – follow-up based on several factors
- Response - appropriate for each hypothesis
End Products from the Committee

- Plausibility assessment about causal role of vaccines, with likelihood rating
- Categorization of appropriate level of public health concern
- Set of comments about potential future activities
Product 1: Plausibility Assessment

- If evidence is adequate, make definitive judgment about causality
- If evidence is limited,
  - Evaluate biologic plausibility
  - Evaluate strength of evidence for competing causes
  - Perform synthesis of evidence and scientific information
  - Formulate a likelihood rating or give a probability judgment
Product 2: Appropriate Level of Public Health Concern

- Plausibility Assessment/likelihood rating
- Significance Assessment
  - Number of persons potentially affected
  - Seriousness of health concern or condition
  - Other
- Categorization of the appropriate level of public health concern (very low – very high)
Product 3: Comments on Potential Future Activities

- Research
- Surveillance
- Communications
- Policy review
Guidance Regarding the Appropriate Public Health Response

- Plausibility assessment with likelihood rating
- Categorization of appropriate level of public health concern
- Set of comments on potential future activities
The Committee is NOT Being Asked to:

- Make public health policy
- Set agency agendas for research, surveillance, communication, or policy
- Make overly general or overly specific comments
Uniqueness of this Committee

- Standing committee – meet 3-4 times per year
- Issue timely, brief and focused reports
  - Within 60 to 90 days of meeting
- Perform more explicit assessment of causality
- Provide appropriate level of public health concern
- Comment on a broader scope of potential public health responses
- IOM more proactive in the dissemination of information to lay and professional audiences