From: (b)(6)
Sent: Fri, 16 Oct 2009 10:23:28 -0400
To: Destefano, Frank (CDC/OD/OCSO)
Cc: Markowitz, Lauri (CDC/CCID/NCHHSTP)
Subject: Fw: CERVARIX approved in US
Attachments: 20091016095208.pdf

Dear Frank:

Attached is the FDA approval letter for Cervarix. We thought it might be useful for you to see what post-marketing studies they have requested.

Best regards,
Peggy

Margaret B. Rennels, M.D.
Executive Director, U.S. Scientific Vaccine Policy
GlaxoSmithKline Biologicals
Suite800
1050 K St. NW
Washington, D.C. 20001
office: 202-715-1026
(b)(6)
fax 202-715-1001
(b)(6)

From: Saddier, Patricia
Sent: Mon, 17 May 2010 20:34:35 -0400
To: Destefano, Frank (CDC/OID/NCPDCID)
Cc: Liaw, Kai-Li
Subject: FW: VSD question
Attachments: ACIP_HPV_Oct 2008.pdf

Dear Frank,

The lead epidemiologist for Gardasil (HPV4 vaccine) at Merck, Dr. Kai-Li Liaw (copied on this e-mail), has a couple of questions on the VSD study for GARDASIL and I thought you might be able to help us.

In the attached ACIP presentation made by the VSD study investigators in October 2008, slide 6 lists the AEs of interest in the VSD study along with the time window for each. We are wondering what the last column entitled "first in what period?" represents. For most AEs, it seems to match pretty closely the time window of interest, but we were wondering why for VTE, the window was 42 days when the "period" column indicates "1 year".

We would greatly appreciate it if you could help us with this question or direct us to some one who could.

Thank you in advance for your help.

Kind regards,
Patricia

Patricia Saddier, MD PhD
Senior Director, Epidemiology
Merck Research Laboratories
351 North Sumneytown Pike, UG1D-60
North Wales, PA 19454-25059
(b)(6)

From: Liaw, Kai-Li
Sent: Monday, May 17, 2010 12:14
To: Saddier, Patricia
Subject: VSD question

Hi Patricia,

Per our discussion, here's the slide deck, please refer to page 6. Thanks so much!

<<ACIP_HPV_Oct 2008.pdf>>

Kai-Li

Kai-Li Liaw
(b)(6)

Vaccine Safety Datalink Project: Monitoring the Safety Of Quadrivalent Human Papillomavirus Vaccine (HPV4)

Advisory Committee on Immunization Practices Meeting, October 22, 2008

Julianne Gee, MPH[1]

Allison Naleway, PhD[2]

Irene Shui, MPH[3]

[1]Center for Disease Control and Prevention, Atlanta GA

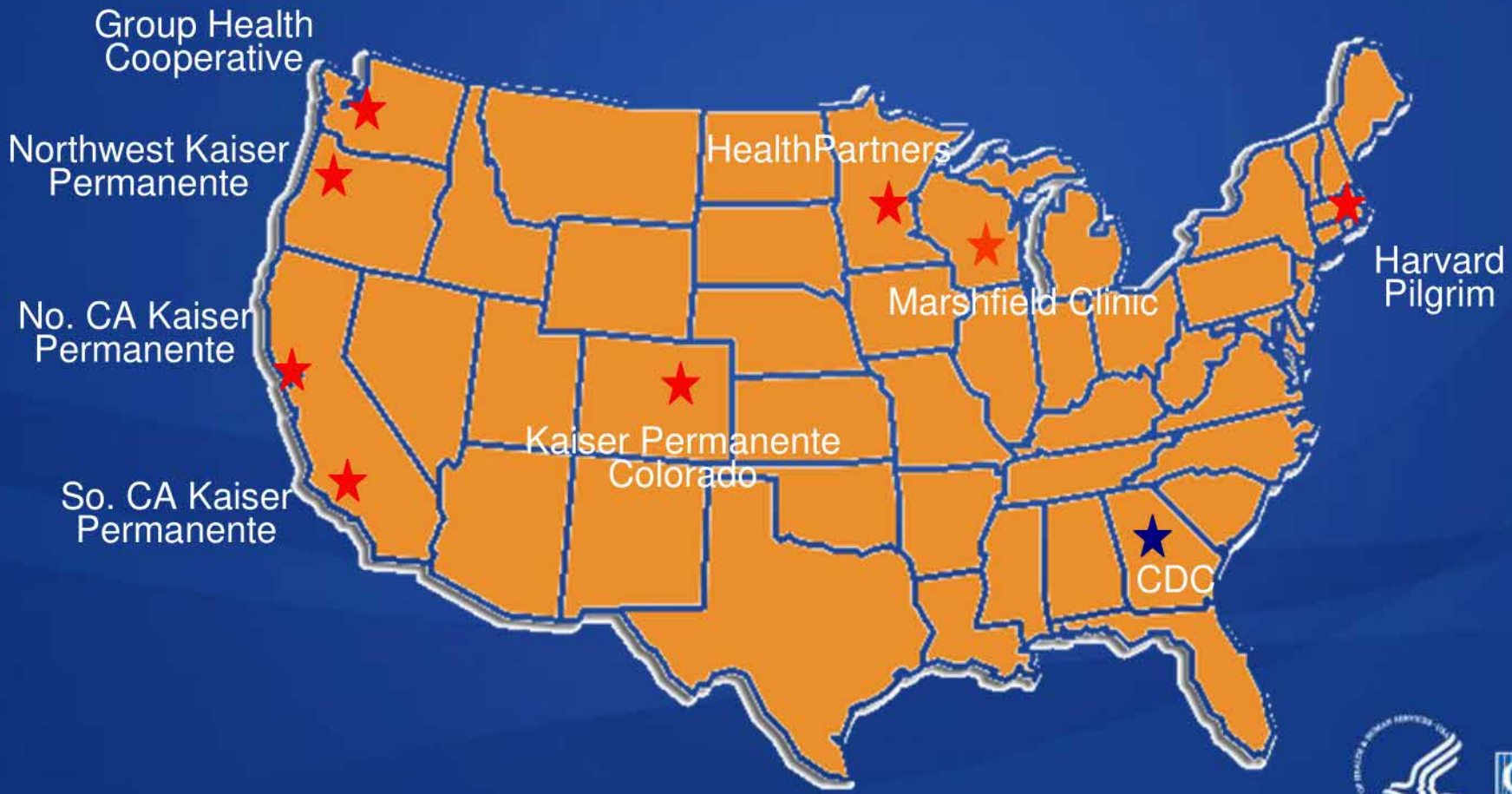
[2] Kaiser Permanente Northwest, Portland OR

[3] Harvard Pilgrim, Boston MA

Vaccine Safety Datalink (VSD)

Collaboration between CDC and 8 managed care organizations

Data from 8.8 million members captured annually (3% of US population)



Vaccine Safety Datalink (VSD)

- Established in 1990 to improve the evaluation of vaccine safety through use of active surveillance and epidemiological studies
  - Addressed limitations of the Vaccine Adverse Event Reporting System (VAERS)
  - Responded to needs identified by two Institute of Medicine reports
- VSD tests hypotheses suggested by VAERS reports and pre-licensure trials

Rapid Cycle Analysis (RCA)

- Alternative to traditional post-licensure vaccine safety study methods, which generally take years to complete
- RCA Studies:
  - Tests specific hypotheses with well-defined outcomes
  - Each week, evaluate the number of events in vaccinated persons
  - Compare it to the expected number of events based on a comparison group
    - Historical or concurrent
  - Weekly analyses with statistical adjustment for multiple looks

Lieu TA, et al. Real-time vaccine safety surveillance for the early detection of adverse events. Med Care. 2007 Oct;45:S89-95.

HPV4 RCA Study

- Objective: Identify associations between HPV4 and a pre-specified list of adverse outcomes in females age 9-26 years
- 7 participating VSD sites
- Females 9-26 yrs
  - Youth: 9-17 yrs
  - Adults: 18-26 yrs
- Data from August 20, 2006-July 20, 2008
  - Allow for late arriving data
- Monitor until:
  - Youth: 350,000 doses
  - Adults: 150,000 doses