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To: Vaccine Safety Work Group and Interested Stakeholders

From: The Keystone Center Team – Janesse Brewer, Brad Sperber, Johanna Raquet, and Amber Brummer

Subject: Salt Lake City Writing Group

Date: April 13, 2010

The Salt Lake City Writing Group meeting was convened by the Vaccine Safety Working Group (VSWG) of the National Vaccine Advisory Committee (NVAC). Individuals from a range of sectors and perspectives met on April 11-13, 2010 in Salt Lake City to provide thoughtful input on the enhancement of the national vaccine safety system. For the purposes of this meeting, participants were asked to bring their experience and expertise to bear on this issue, but were not asked or expected to represent the official views of their organizations of affiliation.

The NVAC advises the U.S. Department of Health and Human Services (HHS) on issues of vaccine policy. In 2008, NVAC formed a Vaccine Safety Working Group (VSWG) with two charges: first, to review and provide comment on the Centers for Disease Control's (CDC) Immunization Safety Office's (ISO) draft Scientific Agenda; second, to review the current federal vaccine safety system. Specific to the second task, the VSWG is charged with developing a White Paper (for consideration and possible adoption by the NVAC) describing the infrastructure needs for a federal vaccine safety system.

As part of these efforts, NVAC committed to meaningful public and stakeholder engagement. For the VSWG's second charge, that process includes both the recently concluded meeting in Salt Lake City and a meeting of a broader group of stakeholders scheduled for June 1, 2010 in Washington, DC.

The accompanying memorandum from the Writing Group provides some highlights of the discussion on April 11-13, 2010.

Please feel free to contact the meeting facilitators, Janesse Brewer or Brad Sperber of The Keystone Center, with any questions about the Salt Lake City 2010 meeting. Janesse may be reached at 970-513-5847 or via e-mail at jbrewer@keystone.org. Brad may be reached at 202-452-1593 or via e-mail at bsperber@keystone.org.

Vaccine Safety Writing Group
April 11th, 12th & 13th, 2010
Salt Lake City, UT

To: Vaccine Safety Working Group and Interested Stakeholders

From: Salt Lake City Writing Group Meeting Participants: Rob Beck, Peter Bell, Sallie Bernard, Guthrie Birkhead, Anna Buchanan, Tawny Buck, Tracy Cron, Vicky Debold, Corry Dekker, Margaret Dunkle, Lance Gordon, Mark Grabowsky, Richard Greenaway, Alan Greene, Barbara Loe Fisher, James Mason, Thomas May, Debbie McCune Davis, Barbara Mulach, Andrew Pavia, Lisa Randall, Bill Raub, Daniel Salmon, Jim Shames, Andrea Sutherland, Zachary Taylor, Jerry Tokars, Collette Young, and Heather Zwickey (see attached list for additional detail)

Re: Salt Lake City Writing Group Meeting on April 11-13, 2010

Date: April 13, 2010

The Salt Lake City Writing Group met for three days of groundbreaking discussions regarding the vaccine safety system. All participants worked respectfully and in good faith. The group identified objectivity, transparency, and evidence-based decision making as highly prioritized attributes of a robust vaccine safety system.

We agreed that an improved safety system would result in the following outcomes:

1. Characterize the safety profile of vaccines and vaccination practice;
2. Detect, prevent, and reduce adverse events in a timely manner;
3. Develop guidance to detect and mitigate the effects of adverse events in individuals;
4. Earn public confidence in the effectiveness of the vaccine safety system and in the safe use of vaccines; and
5. Inform vaccine policy.

Participants agreed that an improved internal assessment system is important and that an external assessment of the vaccine safety system is either essential or acceptable in meeting these outcomes. While there were different views as to the focus and organizational locus of any external assessment and what it would take for it to be adequately independent, it was agreed by participants that it should have the following features:

- Includes diverse expertise relevant to vaccine safety
- Regularly and meaningfully engages the public and stakeholders
- The ability to gain cooperation and response among relevant entities (i.e., has some “teeth”)
- A charge focused on safety, independent of other vaccination program purposes
- Use of rigorous scientific and programmatic evidence

A variety of options for fulfilling this need were discussed throughout the meeting.

The nine Vaccine Safety Working Group (VSWG) members who were present specifically shared that they had learned a great deal in this session and that in some cases, their thinking has shifted over the course of the three days. The VSWG members shared that these conversations would continue to inform their internal deliberations on the Working Group.

On June 1, 2010 the VSWG will host an open stakeholder meeting in Washington, D.C., to gain further feedback from interested stakeholders on the vaccine safety system. The Salt Lake City Writing Group has provided valuable feedback that will help the VSWG further refine materials for the June 1 meeting.

Vaccine Safety Writing Group
April 11th, 12th & 13th, 2010
Salt Lake City, UT

Note:

^ indicates VSWG members.

* indicates NVAC members.

Salt Lake City Writing Group meeting participants were asked to participate as individuals rather than representing their organizations of affiliation.

Robert Beck ^

Member
Advisory Committee on Immunization Practices

Peter Bell

Executive Vice President
Autism Speaks

Sallie Bernard

Executive Director
SafeMinds

Gus Birkhead *^

Deputy Commissioner, Office of Public Health
New York State Department of Public Health

Anna Buchanan

Senior Director, Immunization & Infectious Disease
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Tawny Buck *^

Director, Government Relations
National Vaccine Information Center

Tracy Cron

Member
Alabama Interagency Autism Coordinating Council

Vicky Debold ^

Director, Patient Safety
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Corry Dekker * ^

Medical Director, Stanford Lucile Packard Children's
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Margaret Dunkle

Senior Research Scientist
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Lance Gordon ^

President & CEO
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Mark Grabowsky

Deputy Director, National Vaccine Program Office
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Richard Greenaway

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James Mason * ^

Former Director,
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Thomas May

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Lisa Randall

Associate Executive Director
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Bill Raub ^

Former Deputy Director
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Former Advisor to the Secretary
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Andrea Sutherland

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Zachary Taylor

Regional Health Administrator, Office of Public Health and Science
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Jerry Tokars

Medical Epidemiologist (Team Lead)
Center for Disease Control & Prevention

Collette Young

Oregon Immunization Surveillance & Training Manager
Oregon Public Health Division

Heather Zwickey

Dean of Research
National College of Natural Medicine

Other staff and experts in attendance (not official members of the Writing Group):

Robert Bednarczyk

National Vaccine Advisory Committee Research Analyst

Roger Bernier

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Centers for Disease Control & Prevention

Janesse Brewer

Senior Associate
The Keystone Center

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