Seattle Children's
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MAY 17 2009

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: **Recommendations from Advisory Commission on Childhood Vaccines Regarding National Vaccine Injury Compensation Program**

Dear Secretary Sebelius:

The Advisory Commission on Childhood Vaccines (ACCV) submits this letter to provide you with recommendations to improve the National Vaccine Injury Compensation Program (the Program). The ACCV is a nine-member advisory commission created when Congress enacted the National Childhood Vaccine Injury Act of 1986 (the Act, 42 U.S.C. §§300aa-1 *et seq.*). The ACCV exists to advise and make recommendations to the Secretary of Health and Human services on matters related to the implementation of the Program.

The Act created the Program. The Act's overriding public health objective is elimination of vaccine-preventable illness by encouraging the development, improvement and use of vaccinations. Within that context, the Program exists to stabilize the nation's vaccine supply by providing compensation through the Program for injuries or deaths resulting from administration of certain vaccines recommended for use in children. The Program therefore benefits vaccine manufacturers (industry), vaccine administrators (health care providers) and individuals who claim vaccine-related injuries (petitioners).

For petitioners, the Program was intended to be an appealing "no-fault" alternative to the tort system in which the process of receiving compensation would be faster, less adversarial, and more compassionate. The House Report on the Act called for a compensation program that administered awards "quickly, easily, and with certainty and generosity".

For industry and for health care providers, the Program was intended to provide a broad measure of protection from liability by requiring any person claiming a vaccine-related injury to pursue a petition with the Program before "opting out" to sue a manufacturer or provider directly in state or federal court. The Act also provides certain other protections from civil liability to industry and providers.

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The Program is funded by the imposition of a 75-cent excise tax per disease prevented (per dose), which is paid by the vaccine consumer, collected by the manufacturer, and deposited into the Vaccine Injury Compensation Trust Fund (the Fund). Currently, there appears to be a sufficient balance in the Fund to cover expected needs.

The Program is administered by the Department of Health and Human Services, Health Resources and Services Administration, in conjunction with the Department of Justice and the Court of Federal Claims. Congress intended the Program to be "fair, simple and easy to administer", and "to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury". Accordingly, the Act provides for informal procedural rules and limited discovery. Under the Act, if a petition has not been decided after 240 days (8 months), the petitioner has 30 days to opt out of the Program and pursue state law claims in either state or federal court.

At its November 2008 meeting, the ACCV constituted a workgroup consisting of 6 members to review prior ACCV recommendations to the Secretary and consolidate and present the ACCV's consensus recommendations for immediate changes to improve the functioning of the Program. The workgroup was chaired by the ACCV Chair, a non-affiliated lawyer, and included two health care provider representatives, a representative of the general public, a representative of the general public who is also the parent of a vaccine-injured child, and an attorney who specializes in representing vaccine manufacturers. The workgroup met by telephone several times from November 2008 to February 2009, and in person on March 5, 2009. It carefully studied and discussed issues related to the functioning of the Program and proposals for improvement.

This letter sets forth the recommendations unanimously adopted by the workgroup, which were presented to the ACCV at its meeting on March 6, 2009. After discussion and public comment, **the ACCV voted unanimously to support these recommendations and forward them to you.**

We urge you to adopt these recommendations as your own and present them as legislative proposals to Congress at your earliest convenience. We believe that doing so will ensure the Program remains viable and fulfills its legislative mission. The ACCV would be happy to provide additional information if that would be useful to you, and we appreciate your support of these recommendations.

Very truly yours,

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