



State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

October 31, 2007

CHDP Provider Information Notice No.: 07-14

TO: ALL CHILD HEALTH AND DISABILITY PREVENTION (CHDP)
PROGRAM PROVIDERS AND MEDI-CAL MANAGED CARE PLANS

SUBJECT: VACCINATION IN COCHLEAR IMPLANT RECIPIENTS

On October 10, 2007, the Food and Drug Administration (FDA) issued the enclosed Public Health Notification titled Importance of Vaccination in Cochlear Implant Recipients.

The FDA document contains information on two deaths from meningitis within the past year in children with cochlear implants. It documents the poor immunization rate in the cochlear implant population and provides recommendations and references.

The primary recommendations are as follows:

- Follow the Centers for Disease Control and Prevention (CDC) vaccination recommendations
- - Children with cochlear implants, and potential implant recipients, should receive pneumococcal vaccination under the same schedules that apply to other groups at high risk for invasive pneumococcal disease.
(<http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-hcp.htm>)
 - Health care providers and families should review vaccination records of current and prospective cochlear implant recipients to ensure all recommended vaccines have been received.
- Recognize the signs of meningitis early.
- Diagnose and treat middle ear infections promptly in cochlear implant recipients.
- Consider prophylactic antibiotics preoperatively in children receiving cochlear implants.

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Your continuing participation in the CHDP Program is greatly appreciated. If you have any questions about this Provider Information Notice or other CHDP issues, please contact your local CHDP Program office.

Original Signed by Marian Dalsey, M.D., M.P.H.

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Enclosure



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FDA Public Health Notification: Importance of Vaccination in Cochlear Implant Recipients

Issued : October 10, 2007

Dear Healthcare Provider:

This is to remind you of the increased, life-threatening risk of bacterial meningitis in cochlear implant recipients and **the importance of fully immunizing these patients**. Although all cochlear implant recipients appear to be at some increased risk of bacterial meningitis caused by *Streptococcus pneumoniae*, **those children implanted with cochlear implants that have a positioner are at greatest risk**. The only model with a positioner was withdrawn from the market in July, 2002.

Recent deaths

FDA has become aware of two deaths from meningitis within the past year in children implanted with the cochlear implant with positioner. Neither of these children was fully immunized according to the CDC recommended vaccination schedule (see link below). These children, ages 9 and 11, had completed only part of the recommended pneumococcal vaccinations for their age group. At least one of these children had meningitis caused by a serotype of *Streptococcus pneumoniae* that may have been prevented by proper vaccinations.

Failure to immunize

A recent survey of the Johns Hopkins University cochlear implant patient population, conducted by Dr. John Niparko, revealed that despite repeated information bulletins from the University regarding the importance of vaccination, 29% of the parents/guardians of patients under 2 years of age were uncertain of the child's vaccination status. Vaccination status was unknown in 43% of children older than two years, and 12% were known to be not properly vaccinated. These findings strongly suggest that patients are not receiving vital preventive care that can reduce their risk of this life-threatening illness. FDA is working with the CDC, cochlear implant manufacturers, and professional societies to heighten awareness of the importance of vaccinations in the cochlear implant population.

Recommendations to decrease the risk of meningitis in cochlear implant recipients

- **Follow CDC's vaccination recommendations.** CDC has issued recommendations regarding which vaccines cochlear implant patients should receive and when the vaccines should be given. Because children with cochlear implants are at increased risk

for pneumococcal meningitis, CDC recommends that they receive pneumococcal vaccination under the same schedules that apply to other groups at high risk for invasive pneumococcal disease. These recommendations are available on the CDC's website at <http://www.cdc.gov/vaccines/vpd-vac/mening/cochlear/dis-cochlear-hcp.htm>. They apply to all children with a cochlear implant, with or without a positioner, and to all potential implant recipients. Healthcare providers (including primary care physicians, pediatricians and otolaryngologists) and families should review vaccination records of current and prospective cochlear implant recipients to ensure that the patient is current on all the CDC recommended vaccinations.

- **Recognize the signs of meningitis early.** Cochlear implant recipients, along with their families, educators, daycare and healthcare providers, need to be aware of the signs of meningitis. This can help ensure early detection and treatment of this life-threatening illness. Early intervention is vital in successfully treating the infection and minimizing permanent neurological damage. Early signs of meningitis may include high fever, headache, stiff neck, nausea or vomiting, discomfort looking into bright lights, and sleepiness or confusion. Patients may also present with ear pain and/or ear infection. A young child or infant with meningitis might be sleepy, cranky, or eat less.
- **Diagnose and treat middle ear infections promptly.** In some of the meningitis cases reported to FDA, cochlear implant recipients had signs of middle ear infection (otitis media) prior to surgery or before the meningitis developed. For this reason, according to American Academy of Pediatrics clinical practice guidelines, healthcare providers should diagnose and treat otitis media promptly in patients with cochlear implants. They should also consider antibiotic therapy more readily in this population than others.
- **Consider prophylactic antibiotics.** Healthcare providers should consider prophylactic antibiotic treatment perioperatively in children receiving cochlear implants.

Advice to Patients with Cochlear Implants can be found at <http://www.fda.gov/cdrh/medicaldevicesafety/atp/101007-cochlear.html>.

Additional background information

The original CDC/FDA article on this topic was published in the July 31, 2003 issue of The New England Journal of Medicine (<http://content.nejm.org/cgi/content/full/349/5/435>). The original FDA Notifications on the Risk of Bacterial Meningitis in Children with Cochlear Implants, can be found at <http://www.fda.gov/cdrh/safety/cochlear.html> and <http://www.fda.gov/cdrh/safety/020606-cochlear.html>. The earlier FDA Notifications include additional background information not included in this update.

Reporting cases of meningitis in cochlear implant recipients

We encourage you to report cases of meningitis in cochlear implant recipients. You can report cases directly to the device manufacturer or to MedWatch, FDA's voluntary reporting program. This can be done on line at www.fda.gov/MedWatch/report.htm, by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by returning the postage-paid FDA form 3500 which may be downloaded from www.fda.gov/MedWatch/getforms.htm. You can also report by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Contacting FDA

If you have questions about this notification, please contact Nancy Pressly, Office of

Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 240-276-3357 and we will return your call as soon as possible.

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Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health

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