" <u>Goldman</u> also reports that shortly after communicating on authorship issues with health officials associated with the Centers for Disease Control (CDC) concerning the shingles data and analysis, he was threatened with legal action if he published the manuscript in the medical literature. He said, "Whenever research data and information concerning potential adverse effects associated with a vaccine used in a human population are suppressed and/or misrepresented by health authorities, not only is this most disturbing, it goes against all accepted scientific norms and dangerously compromises professional ethics.""

## http://www.emediawire.com/releases/2003/10/prweb82645.htm

# ATA REVEALS THREAT OF SHINGLES EPIDEMIC FROM VACCINE USE Health Officials Threaten Legal Action Against Researcher

Three different analyses of reported cases of shingles and chickenpox were published today in the October 2003 issue of Vaccine and suggest the threat of a shingles epidemic in the US due to mass vaccination with varicella (chickenpox) vaccine.

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FOR IMMEDIATE RELEASE (PRWEB October 1, 2003

DATA REVEALS THREAT OF SHINGLES EPIDEMIC FROM VACCINE USE Health Officials Threaten Legal Action Against Researcher

Pearblossom, California (PRWEB) October 1 2003-- Three different analyses of reported cases of shingles and chickenpox were published today in the October 2003 issue of Vaccine and suggest the threat of a shingles epidemic in the US due to mass vaccination with varicella (chickenpox) vaccine. Data collected under the CDC-funded Varicella Active Surveillance Project (VASP) of the Los Angeles County Department of Health Services Acute Communicable Disease Control Unit revealed that when chickenpox disease was significantly reduced in a population, there was an unexpectedly high number of shingles cases among unvaccinated children with a previous history of chickenpox. Shingles is usually mild in children and can be severe in adults. Complications from shingles, which is caused by the reactivation of the chickenpox virus that lies dormant in the body, result in about three times the number of hospitalizations and five times the number of deaths as those from chickenpox disease.

The analyses were authored by Gary Goldman, Ph.D., a former research analyst with the VASP, using capture-recapture methods. Goldman worked from 1995 through late 2002 at one of three projects in the nation assigned to actively study the effects of chickenpox vaccine and received reports from three hundred different public and private schools, day cares, and healthcare facilities. He observed that because the vaccine is eliminating chickenpox disease, children and adults no longer receive the natural boost to their immune systems that they received from periodic exposures to the disease. Due to the dramatic decline in chickenpox, children are now experiencing a higher incidence of shingles and Goldman predicts that a large scale increase in shingles incidence will soon become manifest among adults-a group more susceptible to serious complications.

Vaccine manufacturers plan to license a booster "shingles" vaccine to substitute for the boosting that naturally occurred when chickenpox disease was previously circulating in the population. "This will likely lead to endless disease-and-cure cycles," says Goldman. "Varicella vaccination would have been less problematic if all children had the opportunity to gain natural immunity and only those still susceptible at twelve years old were vaccinated."

Goldman also reports that shortly after communicating on authorship issues with health officials associated with the Centers for Disease Control (CDC) concerning the shingles data and analysis, he was threatened with legal action if he published the manuscript in the medical literature. He said, "Whenever research data and information concerning potential adverse effects associated with a vaccine used in a human population are suppressed and/or misrepresented by health authorities, not only is this most disturbing, it goes against all accepted scientific norms and dangerously compromises professional ethics."

Between 1995 and 2000, shingles was not being studied, and positive aspects of vaccination contributed by Goldman were published in the Journal of the American Medical Association (JAMA) and other medical journals. In 2000, after hearing reports that school nurses were seeing cases of shingles in children for the first time, Goldman suggested shingles be added to the active surveillance project. After two years of shingles data collection, Goldman documented the adverse effects that might well be associated with the universal varicella vaccination program. Currently, varicella immunization is mandated in thirty-eight states.

The European journal, Vaccine (Volume 21, Issue 27/28) has devoted eighteen pages to Goldman's three reports. -end-

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## http://www.prweb.com/releases/2003/10/prweb83848.php

STUDY REVEALS IMPORTANT SIDE EFFECT OF MASS VARICELLA VACCINATION OF HEALTHY CHILDREN: Reduction in chickenpox may increase incidence of shingles.

The results of a new study published in the October 1, 2003 issue of the European journal Vaccine indicate that a higher than expected number of shingles cases was reported among children with a previous history of chickenpox-approaching the incidence rate normally seen only in older adults. Results of the study suggest mass vaccination with varicella (chickenpox) vaccine may be responsible for this adverse effect.

PEARBLOSSOM, Calif. (PRWEB)October 8, 2003--- The results of a new study published in the October 1, 2003, issue of the European journal Vaccine indicate that a higher than expected number of shingles cases was reported among children with a previous history of chickenpox. The rates observed approach those normally seen only in older adults. Results of the study suggest mass vaccination with varicella (chickenpox) vaccine may be responsible for this adverse effect. Complications from shingles, which is caused by the reactivation of the chickenpox virus that lies dormant in the body, result in about three times the number of hospitalizations and five times the number of deaths as those from chickenpox disease itself. Shingles, usually mild in children, can be severe in adults.

On March 17, 1995, the U.S. Food and Drug Administration (FDA) approved the live varicella vaccine, and shortly thereafter 38 states mandated that every infant be inoculated at twelve months of age. The CDC-funded Varicella Active Surveillance Project (VASP) of the Los Angeles County Department of Health Services was established to study trends in varicella disease among the 300,000 residents in the Antelope Valley health district. Because this high desert community, including the primary cities of Lancaster and Palmdale, is geographically distinct with few individuals seeking healthcare outside the region, it is nearly ideal for scientists to detect preliminary disease trends.

"Because the vaccine is eliminating chickenpox disease, children and adults no longer receive the natural boost to their immune systems that they received from periodic exposures to the disease," says Gary S. Goldman, Ph.D., author of the study and former research analyst with VASP. "Due to the dramatic decline in chickenpox, children are now experiencing a higher incidence of shingles."

To compensate for this, vaccine manufacturers plan to license a booster "shingles" vaccine to substitute for the natural boost in immunity that occurred when chickenpox disease was previously circulating in the population. Goldman expresses doubts about the effectiveness of this approach to the impending problem.

"This will likely lead to endless disease-and-cure cycles," says Goldman. "Varicella vaccination would have been less problematic if all children had the opportunity to gain natural immunity and only those still susceptible at twelve years-of-age were vaccinated."

Previous research shows that Japanese pediatricians who were exposed to patients with chickenpox demonstrated shingles incidence rates one-half to one-eighth that of the general population. In 2002, researchers in England

and Wales also found a lower incidence of shingles among adults living with children compared to those living without children. According to a spokesperson from the FDA, "There is no legal precedent requiring a vaccine manufacturer to perform studies on individuals who have not received their product."

However, Goldman insists that, "To assess the safety of chickenpox vaccine, continued study of the effect of widespread vaccination on increasing shingles incidence is critical." Goldman hopes this study encourages other investigators to examine shingles rates not only among vaccine recipients, but also among those who have not received vaccine.

Dr. Goldman concludes, "If a clear vaccine-associated increase in shingles is confirmed in further studies in broader populations, this should be considered by public health authorities in evaluating vaccine use strategies."

For more information on the current study, see the three reports published on 18 consecutive pages in Vaccine (Volume 21, Issue 27/28) or contact Gary S. Goldman, Ph.D., at (661) 944-5661 or via e-mail at <u>pearblossominc@aol.com</u>. ###

About Gary S. Goldman, Ph.D.:

From 1995 to 2000, shingles was not studied, and positive aspects of vaccination contributed by Dr. Goldman were published in the Journal of the American Medical Association (JAMA) and other medical journals. In 2000, after hearing reports of school nurses observing cases of shingles in children for the first time, Goldman suggested shingles be added to the active surveillance project. After two years of shingles data collection, Goldman documented the adverse effects that might well be associated with the universal varicella vaccination program.

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http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_ui ds=14505904&dopt=Abstract Vaccine. 2003 Oct 1;21(27-30):4238-42. Related Articles, Links

Varicella susceptibility and incidence of herpes zoster among children and adolescents in a community under active surveillance.

Goldman GS.

P.O. Box 847, Pearblossom, CA 93553, USA. pearblossominc@aol.com

Licensure of varicella vaccine by the US Food and Drug Administration in March 1995 has given rise to concerns that include a potential shift in varicella incidence to susceptible adults and increase in herpes zoster (HZ) incidence. Baseline values prior to widespread vaccination were obtained through distribution of an adolescent survey to all 13 public middle (seventh and eighth grade) schools in the Antelope Valley, CA health district. Based on 4216 respondents aged 10-14 years, varicella susceptibility is 7.7% (95% CI, 6.9-8.5%) and true cumulative (1987-2000) HZ incidence rate is 133 per 100,000 person-years (95% CI, 95-182 per 100,000 person-years).

PMID: 14505904 [PubMed - in process]

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http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_ui ds=14505905&dopt=Abstract

Vaccine. 2003 Oct 1;21(27-30):4243-9. Related Articles, Links

Incidence of herpes zoster among children and adolescents in a community with moderate varicella vaccination coverage.

Goldman GS.

P.O. Box 847, Pearblossom, CA 93553, USA. pearblossominc@aol.com

Active surveillance for herpes zoster (HZ) was conducted for 2 years (2000-2001) in the Antelope Valley community of 312,000 residents among 290 public and private schools, daycares, and healthcare providers. The true ascertainment-adjusted HZ incidence rate is 307 per 100,000 person-years and 138 per 100,000 person-years among children <10 and individuals aged 10-19, respectively. The unadjusted rate among vaccinated children is 9.5 per 100,000 person-years and an estimated 22 per 100,000 vaccine doses. Unvaccinated children with a previous history of varicella may have greater sensitivity to exogenous exposures (boosting) and a poorer cell-mediated response following primary infection relative to older age groups.

PMID: 14505905 [PubMed - in process]

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http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_ui ds=14505906&dopt=Abstract

Vaccine. 2003 Oct 1;21(27-30):4250-5. Related Articles, Links

Using capture-recapture methods to assess varicella incidence in a community under active surveillance.

Goldman GS.

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The Varicella (chickenpox) Active Surveillance Project (VASP) has been conducting active surveillance since 1 January 1995 in the high desert community known as Antelope Valley, CA (population 300,000) among 300 public and private schools, daycares, and healthcare providers. Capture-recapture methods were applied to estimate reporting completeness for 1995 varicella incidence data and these were compared with the national average incidence rates by age reported by the National Health Interview Survey (NHIS). Varicella cases reported among individuals aged <20 years reflect under-reporting in excess of 50%. Despite limitations on accuracy, capture-recapture estimates are a reasonably accurate, quick, and inexpensive approach in epidemiologic studies.

PMID: 14505906 [PubMed - in process]