

## Appendix X. Brief Summary of *Chickenpox: A New Epidemic of Disease and Corruption*

1. Gary S. Goldman, Ph.D., began to report an unexpectedly high shingles incidence rate among children while serving as Research Analyst for the Varicella Active Surveillance Project (VASP), one of three sites selected by the CDC to study the effect of the varicella vaccine on the population.

### Education:

- 1977 B.S. in Engineering, California State University, Fullerton (CSUF)
- 1977 B.S. in Computer Science, CSUF
- 1982 Ph.D. Computer Science, Pacific Western University

### Experience:

- 1995-2002 Research/Analyst for Antelope Valley Varicella Active Surveillance Project (VASP), Los Angeles Department of Health Services, Acute Communicable Disease Control Unit, funded by the Centers for Disease Control and Prevention (Atlanta, GA)
- Editor-in-Chief, Medical Veritas, 2004-2009. Oversaw publication of 200 peer-reviewed medical manuscripts (2,000 pages).

### Peer Reviewer for the following Journals:

- *Journal of the American Medical Association (JAMA)*
- *Vaccine*
- *The American Journal of Managed Care (AJMC)*
- *Expert Review of Vaccines (ERV)*
- *Expert Review of Dermatology (ERD)*
- *Journal of the European Academy of Dermatology and Venereology (JEADV)*
- *British Medical Journal (BMJ)*
- *Research and Reviews in BioSciences*
- *Human and Experimental Toxicology (HET)*

2. Compared to herpes zoster, chickenpox is a relatively benign disease.

- Primary infection caused by the varicella-zoster virus (VZV)
- Typically a benign disease, characterized by a rash that appears in crops.
- Occurs most often among 3- to 8-year olds
- Lesions concentrated on trunk, scalp, and face
- Symptoms resolve in 7 to 10 days.
- Most contagious 1 to 2 days prior to the rash onset.
- Highly contagious, transmitted through the respiratory system.
- Average incubation period is 14 days (but can range from 10 to 21 days after exposure).
- Anti-itch lotions applied to rash.
- Occasionally bacterial infections occur.

3. There are many more serious complications associated with herpes zoster.

- Postherpetic Neuralgia (PHN)
- Postherpetic Itch (PHI)
- Ramsay Hunt Syndrome
- Bell's Palsy
- Meningitis and Encephalitis
- Eye Involvement
- Jaw Involvement
- Leg, Bladder, and Bowel Involvement
- Disseminated Herpes Zoster
- Stevens-Johnson Syndrome (SJS)
- Congenital Varicella Syndrome (CVS)

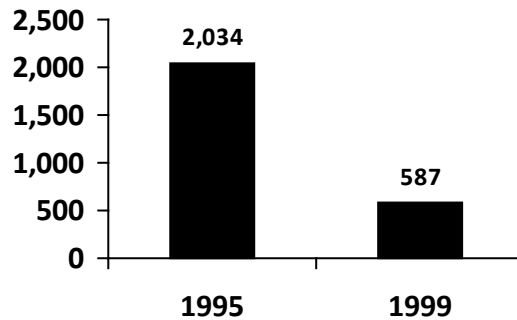
4. Medical costs for herpes zoster are 4 to 5 times higher than those for varicella. So a small increase in shingles incidence could easily offset any savings due to decreases in chickenpox.

Description	Varicella (Chickenpox)	Herpes Zoster (Shingles)
No. of Cases	4 million	1 million
Hospitalizations	11,000	32,000
Deaths	100 <sup>1</sup>	400 to 500
Medical Costs	\$275 million	\$1.1 billion <sup>2</sup>
Medical Costs	25%	75%

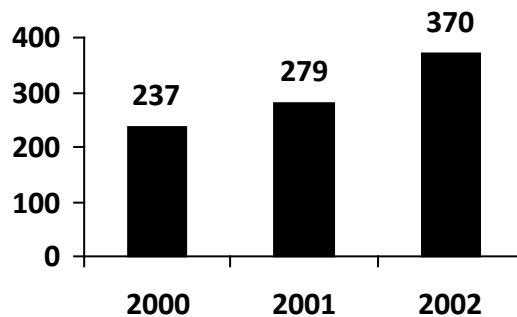
<sup>1</sup>There is a greater chance of a person dying by being struck by lightning in the U.S. (National Oceanic & Atmospheric—NOAA—Technical Memorandum NWS SR-193) than of a child dying from contracting chickenpox.

<sup>2</sup>Health care utilization and cost burden of herpes zoster in a community population. Yawn BP, Itzler RF, Wollan PC, Pellissier JM, Sy LS, Saddier P. Mayo Clin Proc 2009 Sep.;84(9):787-794.

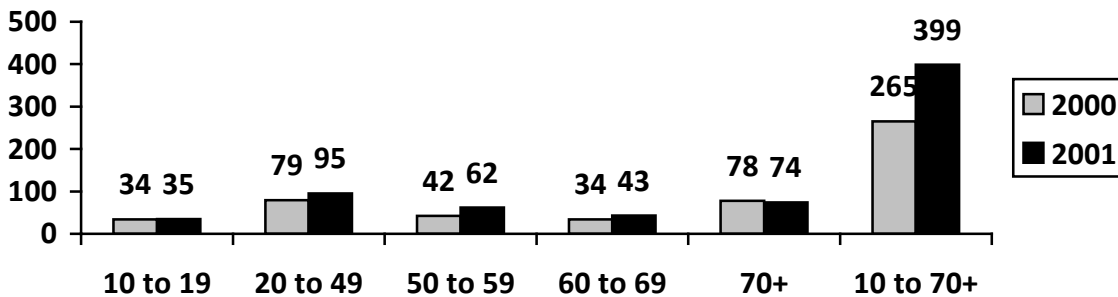
5. There was an 80% decrease in chickenpox cases reported to VASP from 1995 to 1999. All such positive trends reported by Goldman were published by VASP and CDC.



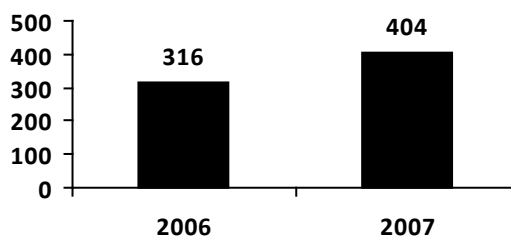
6. There was a statistically significant increase in adult shingles cases reported to VASP among adults aged 20 years and older from 2000 to 2002. The 56.1% increase in reported shingles cases from 237 in 2000 to 370 in 2002 yields a rate ratio of 1.4 (95% C.I. 1.2-1.7).



7. Increases in cases of shingles reported to Antelope Valley VASP occurred in every age category (except 70+) from 2000 to 2001.



8. Verified case reports of shingles among adults aged >50 increased 27.5% from 316 cases in 2006 to 404 cases in 2007. The incidence rate of HZ among adults aged 50 to 59 years increased 38%, from 2.6 cases per 1,000 to 3.6 cases per 1,000. [Based on Table 36 in Antelope Valley, VASP Annual Report]



9. Goldman was not permitted to contact 10 individuals with shingles to follow up on recurrent cases and the section of his report on shingles that established the shingles incidence rate among children prior to the vaccine, was deleted in its entirety.

**The entire narrative of this paper was accepted word-for-word as Goldman composed it; however, the entire section on herpes zoster was deleted without explanation:**

**Varicella susceptibility among adolescents in an active surveillance site. Maupin T, Goldman G, Peterson C, Mascola L, Seward J, Jumaan A, 36th National Immunization Conference of the CDC, May 1, 2002, Denver, Colorado.**

10. Goldman resigned after nearly 8 years serving as Research Analyst for VASP since he could not study the impact of varicella vaccination objectively. **Goldman’s Letter of Resignation stated:**

“When research data concerning a vaccine used in human populations is being suppressed and/or misrepresented, this is very disturbing and goes against all scientific norms and compromises professional ethics.”

11. When Goldman sought to independently publish several manuscripts following his resignation, Dr. Laurene Mascola, Acute Communicable Disease Control Unit, Los Angeles Department of Health Services, had the Los Angeles legal department issue Goldman a notice to “Cease and Desist Publication” in a medical journal.



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VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

**RE: Varicella Active Surveillance Project**

**Dear Mr. Goldman,**

**This letter is notice to you to cease and desist in your efforts to publish or disseminate any information gathered as part of your participation on the VASP.**

12. Goldman’s attorney responded to this notice, firmly stating Goldman’s intention to proceed with publication in the best interest of public health and safety. The Los Angeles legal department did not respond further to Goldman’s attorney. Additionally, there seemed to be conflicts of interest: the CDC vaccine preventable disease group that promoted vaccination was the same group that oversaw vaccine monitoring of safety.

In addition Goldman’s attorney provided this counsel to the L.A. County legal department:

- (a) if your client persists in its efforts to restrain his findings,
- (b) if his findings enhance the public health, safety, and welfare,
- (c) if by seeking to restrain him from imparting valuable information concerning the lack of safety and effectiveness of the pharmaceutical being reported upon, and
- (d) if the County of Los Angeles has in any way been enriched by its participation in any study the results of which it seeks to restrain in this manner or any other manner whatsoever,

then he should consider litigation under the state and federal False Claims Acts.

13. Goldman independently published three manuscripts<sup>1,2,3</sup> after overcoming the notice to “Cease and Desist” initiated by Dr. Laurene Mascola, Acute Communicable Disease Control Unit, Los Angeles Department of Health Services. Since VASP with funding from CDC was a public-funded study, data was not confidential and was available to any citizen through the Freedom of Information Act (FOIA).

<sup>1</sup>**Varicella susceptibility and incidence of herpes-zoster among children and adolescents in a community under active surveillance.** Goldman G. Vaccine, 2003 Oct. 1; 21(27-30):4238–42.

<sup>2</sup>**Incidence of herpes-zoster among children and adolescents in a community with moderate varicella vaccination coverage.** Goldman G. Vaccine, 2003 Oct. 1; 21(27-30):4243–9.

<sup>3</sup>**Using capture-recapture methods to assess varicella incidence in a community under active surveillance.** Goldman G. Vaccine, 2003 Oct 1; 21(27-30):4250–55.

14. Some of the same authors that attempted to have Goldman “Cease and Desist” publication and who wrote a “Scientific Commentary” explaining (incorrectly) why Goldman’s analysis of incidence rates (published in 2005) were in error, wrote a paper in 2009 using methods similar to what Goldman outlined and derived nearly the same shingles incidence rates that Goldman derived in 2002 (see Table below). Goldman realized that the varicella surveillance project did not achieve 100% enumeration of all shingles cases, and in fact, there was approximately 50% underreporting. Taking into account this under-reporting, Goldman reported an ascertainment-adjusted shingles incidence rate of 28 cases per 100,000 person-years among vaccinated children aged 1 to 9 years. A recent study (Tseng HF, Smith N, Marcy SM, Sy LS, Jacobsen SJ. Incidence of herpes zoster among children vaccinated with varicella vaccine in a prepaid health care plan in the United States, 2007, 2008; *Pediatr Infect Dis J.*, 2009 Dec;28(12):1069-72) similarly reports the shingles incidence rate of 27.4 per 100,000 person-years (95% C.I. 22.7–32.7) based on 172,163 vaccinated children with overall follow-up of 446,027 person-years, aged less than or equal to 12 years.

**Table comparing incidence rates derived by Goldman vs. VASP/CDC**

Category (age in years)	Cumulative 2000-2006 HZ incidence <sup>1</sup> (95% C.I.)	Cumulative 2000-2002 HZ incidence <sup>2</sup>	
		Uncorrected (95% C.I.)	Ascertainment- Corrected
Vaccinated, 1-9	19 (15-25)	14 (9-21)	28
Natural Disease, 1-9	239 (193-295)	223 (180-273)	446
Natural Disease 10-19	69 (61-77)	61 (51-72)	122

<sup>1</sup>**The Incidence and Clinical Characteristics of Herpes Zoster Among Children and Adolescents After Implementation of Varicella Vaccination.** Civen R, Chaves S, Jumaan A, Wu H, Mascola L, Gargiullo P, Seward JF. *The Pediatric Infectious Disease Journal*, 2009 Nov; 28(11):954-959.

<sup>2</sup>**Universal Varicella Vaccination: Efficacy Trends and Effect on Herpes Zoster.** Goldman GS. *International Journal of Toxicology*, 2005 Jul/Aug; 24(4):203-213.

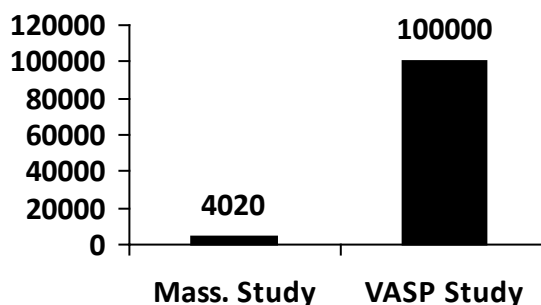
15. CDC attempted to suppress publication of Goldman’s cost-benefit analysis of varicella vaccination taking into account the closely related shingles epidemiology (*Vaccine*, 2005 May; 23(25):3349-55). Elsevier, publishers of *Vaccine*, postponed this manuscript from print for over 1-year based on a single phone call from CDC.

16. Goldman objectively published the complete data, not just the positive results. This included studies demonstrating deleterious effects of varicella and MMR vaccination.

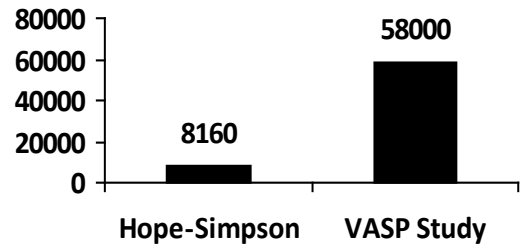
- **An investigation of the association between MMR vaccination and autism in Denmark.** Goldman G, Yazbak EF, *Journal of Association of American Physicians and Surgeons*, Fall 2004; 9(3):70–5.
- **Response to Letter to Editor by Jumaan: Goldman’s role in the Varicella Active Surveillance Project.** Goldman GS. *Vaccine*, 2004 Sep; 22(25-26):3232–6.
- **Universal varicella vaccination: Efficacy trends and effect on herpes-zoster.** Goldman GS. *International Journal of Toxicology*, 2005 July-Aug.;24(4):205–13.
- **The Case against Universal Varicella Vaccination.** [Commentary] Goldman GS. *International Journal of Toxicology*, 2006 Sept.-Oct.,25(5):313–17.

17. Goldman learned that the study that Dr. Jane Seward quoted as “showing no increase in shingles” was too small and had insufficient statistical power to support Dr. Seward’s claim of “no increase”. Yet, shingles incidence data from VASP were often criticized and ignored.

Population of 1-19 year-olds in two different shingles studies:  
Massachusetts Dept. of Public Health vs. Antelope Valley Active Surveillance Project (VASP)

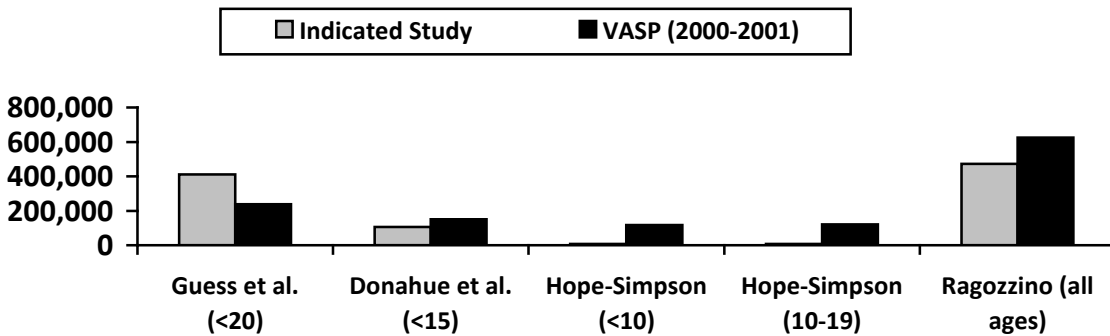


18. At one point VASP superiors suggested the longitudinal (16-year) study by Hope-Simpson provided better shingles data than that collected by VASP. Dr. Hope-Simpson reported 6 cases of shingles among children less than 10 years old in the city of Cirencester, England with a population of approximately 510 children. However it would have taken Hope-Simpson over 180 years to accumulate the data that VASP collected in 1 year!

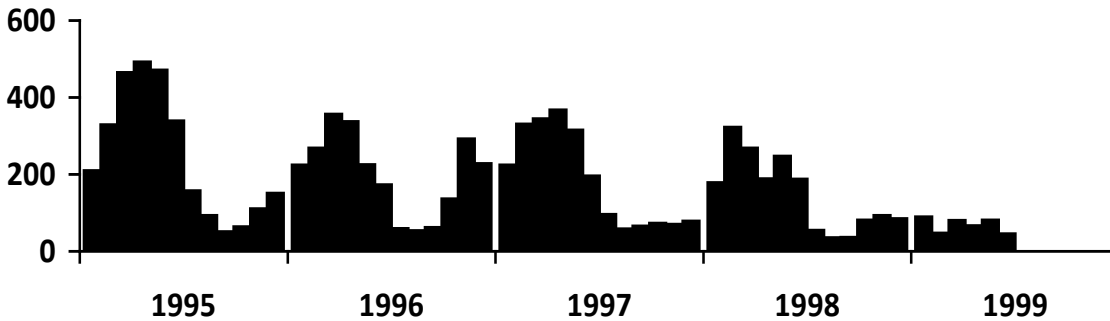


**Observation time (in person-years) among children less than 10 years old.**

19. VASP superiors suggested other studies as having better shingles data; however only one study (by Guess *et al.*) had more observation time than VASP.

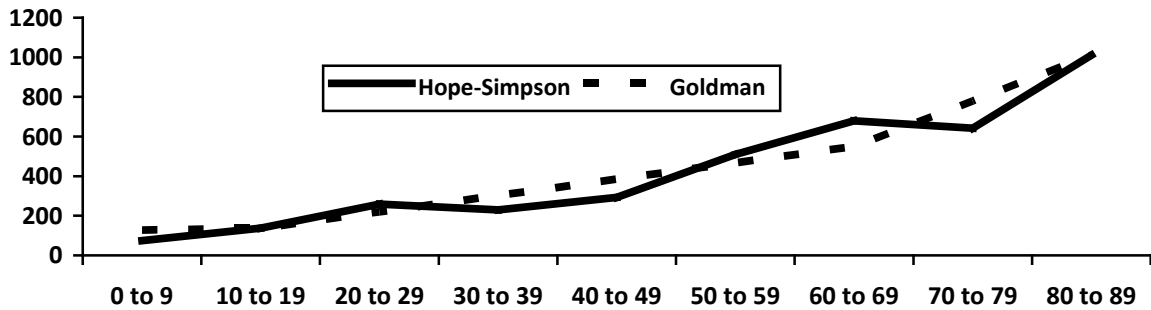


20. Goldman described the seasonal (monthly) variations in varicella in terms of ambient outside air temperature and population density (student enrollments) and discerned early trends in shingles once exogenous (outside) exposures (boosts) became rare (after 1999).



21. Dr. Hope-Simpson in 1965 suggested the importance of varicella outbreaks in the community contributing boosts to the immunity of adults to help suppress or postpone shingles: “The peculiar age distribution of zoster may in part reflect the frequency with which the different age groups encounter cases of varicella and because of the ensuing boost to their antibody protection have their attacks of zoster postponed.” (Hope-Simpson RE. The nature of herpes zoster: a long-term study and a new hypothesis. Proc R Soc Med 1965 Jan;58:9-20.)

22. Larger population studies of shingles incidence in Europe have closely agreed with the shingles rates determined by Hope-Simpson. Goldman determined that the true incidence rate among those children aged 0 to 9 with a previous history of chickenpox was the same as the incidence in the next age category (10-19 years old). Shingles was higher in adults as compared to children, since adults had fewer exogenous (outside) exposures to children with chickenpox. The graph below shows the shingles incidence rates determined by Dr. Hope-Simpson.



23. When exogenous exposures (boosts) became rare, the vaccine was less effective and children soon needed a booster varicella vaccination. The vaccine demonstrated peak efficiency in 1999 (known as the “honeymoon” effect) because vaccinated children just recently had also been boosted by outbreaks of varicella that occurred in the community. By 2002, vaccine Efficacy had dropped to 50%.

Year of Study	Vaccine Efficacy % (95% C.I.)
1997	87 (75-93)
1998	94 (83-98)
1999	96 (83-99)
2000	86 (74-92)
2001	74 (58-84)
2002	50 (14-80)

24. Several recent studies of increasing shingles costs and incidence rates are noteworthy:

**Herpes zoster-related hospitalizations and expenditures before and after introduction of the varicella vaccine in the United States.** Patel MS, Gebremariam A, Davis MM. Infect Control Hosp Epidemiol. 2008 Dec.; 29(12):1157-1163.

Since the introduction of the chickenpox vaccine, hospitalization costs for complications of shingles have increased by more than \$700 million annually for adults 60 years and older.

**The incidence of varicella and herpes zoster in Massachusetts as measured by the Behavioral Risk Factor Surveillance System (BRFSS) during a period of increasing varicella vaccine coverage, 1998-2003.** Yih WK, Brooks DR, Lett SM, Jumaan AO, Zhang Z, Clements KM, Seward JF. BMC Public Health. 2005 Jun 16;5(1):68.

As varicella vaccine coverage in children increased, the incidence of varicella decreased and the occurrence of herpes zoster among adults increased 90%.

**Evidence of increasing frequency of herpes zoster management in Australian general practice since the introduction of a varicella vaccine.** Grant KA, Carville KS, Kelly HA. Med J Aust. 2010 Oct 18;193(8):483.

These updated data support the conclusions reached by both groups of researchers that there has been a decrease in varicella cases and a rise in HZ cases in Australian general practice consultations since the introduction of a varicella vaccine in 2000. The trend in HZ-related MMDS consultations showed an increase in the annual average rate from 1.7/1000 consultations in 2000 to 2.7/1000 consultations in 2007 ( $P < 0.001$ , 2000–2007) and to 3.4/1000 consultations for the first half of 2010 ( $P = 0.020$ , 2007–2010). There was a substantial increase in the HZ-related consultation rates for people aged 70–79 years and 80+ years.

25. Another study showing a 28% increase in shingles incidence from 1996 to 2001.

**A Population-Based Study of the Incidence and Complication Rates of Herpes Zoster Before Zoster Vaccine Introduction** (Department of Research, Olmsted Medical Center, 210 Ninth St SE, Rochester, MN, USA) Yawn BP, Saddier P, Wollan PC, St Sauver JL, Kurland MJ, Sy LS. *Mayo Clin Proc* 2007 Nov;82(11):1341-1349.

**RESULTS:** A total of 1669 adult residents with a confirmed diagnosis of HZ were identified between January 1, 1996, and December 31, 2001. Most (92%) of these patients were immunocompetent and 60% were women. **When adjusted to the US adult population, the incidence of HZ was 3.6 per 1000 person-years (95% confidence interval, 3.4–3.7), with a temporal increase [of almost 30%] from 3.2 to 4.1 per 1000 person-years from 1996 to 2001.**

26. A CDC study<sup>1</sup> that showed no increase in shingles incidence was severely criticized<sup>2</sup> since it was conducted among a population where varicella vaccination had not as yet been widespread in the community.

<sup>1</sup>Jumaan AO, Yu O, Jackson LA, Bohlke K, Galil K, Seward JF (2005). "Incidence of herpes zoster, before and after varicella-vaccination-associated decreases in the incidence of varicella, 1992-2002". *J Infect Dis.* 191 (12): 2002–2007. PMID 15897984.

<sup>2</sup>Whitley RJ (2005). "Changing dynamics of varicella-zoster virus infections in the 21st century: the impact of vaccination". *J Infect Dis.* 191 (12): 1999–2001. PMID 15897983

27. The Zostavax vaccine for adults aged 60 years and older provides a boost to the immune system of adults that helps suppress or postpone the onset of shingles. This boost was previously available at no cost through exposure to children in the community with chickenpox.

At \$168 per dose of Zostavax® (Shingles Vaccine)	
Cost to prevent 1 case of Shingles	\$9,912
Cost to prevent 1 case of PHN—mild to severe	\$60,480
Cost to prevent 1 case of PHN—moderate to severe	\$168,000

Table based on study by Oxman MN, Levin MJ, Johnson GR, Schmader KE, Straus SE, Gelb LD, *et al.* A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. *N. Engl. J. Med.* 2005;352:2271–2284.



28. Concluding comments: Prior to the universal varicella vaccination program, 95% of adults experienced natural chickenpox (usually as school aged children)—these cases were usually benign and resulted in long term immunity. This high percentage of individuals having long term immunity has been compromised by mass vaccination of children which provides at best 70 to 90% immunity that is temporary and of unknown duration—shifting chickenpox to a more vulnerable adult population where chickenpox carries 20 times more risk of death and 15 times more risk of hospitalization compared to children. Add to this the adverse effects of both the chickenpox and shingles vaccines as well as the potential for increased risk of shingles for an estimated 30 to 50 years among adults. The Universal Varicella (Chickenpox) Vaccination Program now requires booster vaccines; however, these are less effective than the natural immunity that existed in communities prior to licensure of the varicella vaccine. Routine vaccination against chickenpox has produced continual cycles of treatment and disease.