Interview with Gary Goldman, PhD
on CDC suppression of undesirable vaccine data

The CDC is a U.S. public health agency that many people trust to provide accurate information about important health-related issues. Gary Goldman, PhD is a computer scientist who taught statistics, digital logic design and switching theory—and other graduate and undergraduate courses—as an Associate Professor in the Quantitative Methods and Engineering departments at California State University, Fullerton. Because he had considered CDC to be the gold standard for objective science, in 1995 he welcomed the opportunity to serve as Research Analyst on the CDC-funded Antelope Valley Varicella Active Surveillance Project (VASP). Gradually, however, his views changed and after serving eight years at his post, he resigned to avoid participating in what he perceived was research fraud.

Dr. Goldman's numerous published studies on chickenpox and shingles demonstrate his advocacy for impartiality and accountability in public health. He was recently interviewed about his employment with the CDC-sponsored VASP. According to Goldman, the CDC suppressed or disallowed deleterious vaccine data from being published and engaged in other acts of questionable scientific integrity. Goldman substantiates these claims with compelling evidence. The full interview is provided below.

Neil Miller: You are an expert on the varicella-zoster virus, the microorganism associated with chickenpox and shingles (herpes zoster). How did you get started?

Gary Goldman, PhD: In January 1995, I was hired by *Vestex Human Resource Systems* in behalf of the Los Angeles County Department of Health Services, Acute Communicable Disease Control Unit, to serve as the sole Research Analyst on the CDC-funded Antelope Valley Varicella Active Surveillance Project (VASP). This project's mission was to perform epidemiological studies and monitor the effects of the universal varicella vaccination program on the 300,000 residents comprising the study population within the Antelope Valley region (principally two cities, Lancaster and Palmdale in California).

NM: What were your responsibilities?

GG: I designed and implemented VASP's database of demographic and clinical variables and developed programs to perform all statistical and data analyses associated with the project. From the project onset, I was encouraged by the Co-Principal Investigators to pursue any analyses and studies that might be suitable for publication. In fulfillment of this directive, I authored and co-authored studies that highlighted positive aspects of the varicella vaccination program. These studies were quickly approved by CDC/VASP and subsequently presented and/or published.[1-11] However, my investigation of HZ incidence rates and other deleterious findings were either suppressed or disallowed.[12-20]

NM: Do you believe that the CDC engaged in scientific misconduct?

GG: The CDC obscured the immunologic-mediated link between universal varicella (chickenpox) vaccination and HZ (shingles) epidemiology, especially concerning increased HZ incidence rates among individuals with a history of natural varicella. The CDC perpetuated a false narrative regarding the role that universal varicella vaccination played in reducing exposures to wild-type varicella, which provide natural immune boosts helping to prevent or postpone the reactivation of the varicella-zoster virus as HZ.

NM: How did you respond to the suppression of undesirable findings?

GG: So as not to be a participant in what I perceived as research fraud, I resigned after eight years, in October 2002. This would allow me to publish all VASP data in the absence of CDC and VASP sponsor bias, including preliminary evidence of the deleterious impact of the universal varicella vaccination program on the closely related HZ epidemiology.[12,13,15-20]

NM: Chickenpox is a relatively harmless disease. Yet, in 1995 the chickenpox vaccine was licensed by the FDA and recommended by the CDC for universal use in the United States. Was that a good idea?

GG: The varicella vaccine was licensed despite prior concerns that exogenous exposures to wild-type varicella provided subclinical immune boosts to inhibit the reactivation of varicella-zoster virus as HZ in people who had previously contracted varicella. In fact, this was acknowledged in the *Summary for Basis of Approval Agreement* between the Food and Drug Administration (FDA) and Merck (the varicella vaccine manufacturer): "There is...concern that universal vaccination might result in increased rates of herpes zoster in vaccinated and unvaccinated individuals."[21]

NM: If there were legitimate concerns that a universal chickenpox vaccination program might increase shingles rates, how was this vaccine approved?

GG: Despite concerns acknowledged by the FDA, Merck, and other health authorities regarding the overall effect that a loss of exogenous boosts following universal varicella vaccination might have on rates of HZ, universal varicella vaccination was adopted in the United States primarily based on the cost savings from parental time lost from work to care for a child with chickenpox.[22]

NM: That doesn't seem like a sufficient or sound rationale. Chickenpox is normally benign in childhood and there's evidence that it provides health benefits later in life.

GG: Yes. Three assumptions regarding the cost-effectiveness of a routine varicella vaccine for every child, that all proved false, were also utilized by health authorities to justify the universal varicella vaccination program:

Assumption 1: A single varicella vaccine would be sufficient to confer long-term immunity. *Reality:* Since 2006, two doses have been required because efficacy induced by the single-dose protocol declined rapidly each year following vaccination due to diminished exogenous boosting.

Assumption 2: The universal varicella vaccination program would be cost-effective at $35 per dose, just one dose required.[22] *Reality:* A booster vaccine has been required for several years, costing over $285 for the two doses at current CDC pricing or $342 based on discounted Walgreens retail pricing.[23] The program is no longer cost-effective.

Assumption 3: Universal varicella vaccination would have a negligible impact on the closely related HZ epidemiology. *Reality:* HZ incidence rates among individuals with a history of varicella significantly increased following universal varicella vaccination. In fact, to mitigate the increasing HZ incidence in adults aged 50 years and older, costly single-dose and two-dose HZ vaccines were introduced in 2006 and 2017, respectively. The HZ vaccine provides limited immunologic boosting which was previously achieved naturally, for free, by an adult's exposure to the circulating wild-type varicella-zoster virus.

NM: I remember when the chickenpox vaccine manufacturer developed a shingles vaccine to prevent cases of shingles that were being caused by their chickenpox vaccine. That's a lucrative business plan.

GG: A continual cycle of disease and treatment.

NM: You were hired to monitor the effects of the universal varicella vaccination program on the Antelope Valley population and conduct epidemiological studies under the CDC-funded Varicella Active Surveillance Project. Is that correct?

GG: Yes, I was encouraged to pursue any analyses and studies that might be suitable for publication but was barred from publishing significant findings that showed negative health outcomes associated with the program.

NM: So, undesirable findings were suppressed. Do you have evidence of malfeasance, research bias, or scientific misconduct?

GG: Yes. When the Los Angeles County Department of Health Services, Acute Communicable Disease Control Unit, entered into a cooperative agreement with the CDC, no directive existed for VASP to initiate active surveillance of HZ, so only data on varicella was initially collected *with no corresponding baseline HZ incidence data for the Antelope Valley study region during the early varicella vaccine post-licensure years* 1995 through 1999. I recommended that collecting cases of HZ be adopted as part of active surveillance at the close of VASP's first five-year grant cycle. Although CDC approved HZ active surveillance starting January 1, 2000, a lack of HZ surveillance from the inception of this project is suggestive of either incompetence or misconduct by health authorities, especially since the FDA was fully aware that HZ rates were likely to increase following universal varicella vaccination, as noted in their *Summary for Basis of Approval Agreement* with Merck and in a 1995 special report written by FDA scientists and published in the *Journal of Pediatrics:*

> The incidence of zoster in vaccinated and unvaccinated individuals might increase after universal immunization. There is evidence that reexposure to natural chickenpox boosts cellular immunity and potentially reduces an individual's likelihood of having zoster. Vaccine-induced herd immunity will reduce exposure to wild-type varicella; mathematical modeling indicates that the frequency of zoster in adults could increase.[24]

Since the FDA was fully aware that HZ rates were likely to increase following universal varicella vaccination, *active surveillance of HZ should have been initiated at the start of the universal varicella vaccination program concurrent with active surveillance of varicella.*

NM: So you were aware, and health authorities suspected, that if the universal varicella vaccine program became successful at reducing the incidence of chickenpox, rates of shingles would likely increase. Let's talk about how the CDC prohibited you from publishing important data on the potential harmful effects of the universal varicella vaccination program.

GG: On November 28, 2000, I informed Dr. Jane Seward, CDC Varicella Chief, that the HZ incidence rate among children aged less than 10 years with a history of varicella was approaching the high HZ incidence rate reported in older adults (aged 50-59 years). I also noted that, as vaccination programs continue to reduce the incidence of varicella, adults will increasingly fail to receive natural immune boosts normally obtained from wild-type varicella circulating in the community.[25] I alerted Seward of my concern that *"there*

will be dramatic increases in zoster among adults as mandatory varicella vaccination programs are instituted."[25]

NM: How did the CDC Varicella Chief respond to your concern?

GG: Seward claimed that "internal boosting, not external boosting, maintains immunity,"[26] despite prior evidence that *exogenous* exposures play the dominant role in boosting immunity, as shown in studies by Arvin *et al.*,[27] Terada *et al.*,[28] Gershon *et al.*,[29] and Solomon *et al.*[30] Later studies[31-33] provided additional evidence that exogenous exposures are the most significant factor. (If Seward's statement were correct, then diminished exogenous exposures resulting from universal varicella vaccination would have little or no impact on HZ incidence rate increases.) Seward asserted that the data I reported was inconclusive and premature for evidence of an increase in HZ, and, "unfortunately, we do not have baseline data to use for interpreting the incidence."[34]

NM: But that's because the CDC failed to initially undertake collection of baseline shingles data, right?

GG: Yes. This statement by the CDC's Varicella Chief was true only because *the CDC itself was negligent in not requiring VASP to collect baseline HZ data at the start of the project in 1995.*

NM: So you didn't have baseline data on shingles. How did that affect your analyses?

GG: A lack of baseline HZ data did not affect my analyses of the relative age-specific HZ incidence rates reported by VASP in 2000 and thereafter. Children aged 1-9 years with a history of varicella were afflicted with HZ at a rate 16 times greater than vaccinated children (unadjusted relative risk, RR = 16.2, 95% CI 10.1 - 25.9). Additionally, VASP HZ case reports among adults aged 20-69 years increased 28.5% from 2000 to 2001 (paired t-test: $P < 0.042$, $t = 2.95$, $df = 4$).[11,19]

NM: So shingles rates were starting to increase as suspected. Did you have enough data to publish your findings?

GG: HZ data collected by VASP from the Antelope Valley study population had a sample size and observation times comparable to other historical studies reporting HZ incidence rates,[35-38] so it was suitable for publication despite its *unfavorable* findings. Seward claimed that VASP HZ data (2000-2002) were too preliminary for publication, yet she sought to publish preliminary VASP data showing trends in declining varicella incidence from 1995 to 1999—a *favorable* finding based on just three years of data, 1997-1999 (since vaccine uptake from 1995 to 1996 was negligible and could not have impacted varicella incidence trends). In addition, these downward trends were confounded by a naturally occurring four-to-five-year cycle in varicella incidence that peaked in 1995. The *New England Journal of Medicine (NEJM)* rejected Seward's study on the grounds that it did not contribute anything substantially new to the current understanding of varicella.

NM: So your unfavorable data on rising shingles rates was rejected by Dr. Seward for publication because it was considered preliminary yet she sought to publish favorable preliminary data on the declining incidence of chickenpox. How did you react?

GG: In February 2001, I reached out to Dr. Philip R. Krause, Lead Research Investigator at the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research. On February 28, 2001, Krause stated that "the most intriguing zoster-related issue is the one that [Goldman] is working on, which is the question of how continuous re-exposure influences zoster rates."[39] Krause had more to say on this topic:

> If exogenous exposures contribute heavily to maintenance of immunity, there is the potential [as a result of universal varicella vaccination] to see an increase in wild-type shingles in the unimmunized—and potentially also the immunized—as wild-type exposures decrease."[39]

Yet, Seward had previously stated to VASP Co-Principal Investigators that questions related to the effects of the varicella vaccination program on HZ were not designed to be answered by Antelope Valley VASP. I did not agree with this logic since I had previously proposed HZ surveillance for that very purpose.

NM: You co-authored several papers with Dr. Seward and VASP Co-Principal Investigators. Were you ever conflicted regarding data that was, or was not, included? Also, how did Dr. Seward respond to *NEJM* declining to publish her study?

GG: I was always candid about my concerns. After *NEJM* rejected Seward's paper, she sought to have it published in the *Journal of the American Medical Association (JAMA)*.[8] The editors required that each co-author approve the paper. However, on March 1, 2001, I wrote a letter to Seward alerting her to several of my concerns,[40] including the most recent data from Antelope Valley showing an unusually high HZ incidence rate in year 2000 among children with a history of natural varicella which was several-fold higher than published historical pre-licensure rates. Thus, I informed her that I objected to the paper's conclusion stating that the positive effects of the varicella vaccination program were "reassuring" while nothing was mentioned about the potential harmful effects associated with the closely related epidemiology of HZ. On the same date, I wrote a separate letter to Teresa Maupin (Antelope Valley VASP Project Director), describing my concerns:

> I cannot in good conscience sign off on the authorship sheet and will not regret having my name removed from authorship. I have seriously contemplated and considered the paper (which is now one year out of date) and find that it fails to consider trends and data patterns throughout 2000 and continuing into 2001 that are contrary to those depicted in the paper and that are a legitimate cause for concern. I do not believe I am alone in my concerns and feel the use of "reassurance of continued vaccination" ignores potential deleterious issues that are far from being resolved. Based on some 40 to 50 articles I have studied and read concerning varicella and HZ, I know there are numerous physicians and other objective researchers that have similar concerns. I have always used the phrase "correct me if I am wrong" but even to this novice the CDC appears biased and "pro-vaccine" no matter what the consequences.[41]

NM: How did the Project Director respond to your legitimate concerns?

GG: In a private conversation, Teresa Maupin told me that if I did not sign off on the paper I would cause embarrassment to people at the CDC and VASP and she made a verbal promise that if I complied then VASP would publish data on HZ in the near future.

NM: Despite your many challenges, did you stop pursuing publication of your findings?

GG: No. On May 4, 2001, Dr. John Glasser, the CDC Disease Modeler with whom I had collaborated with on the relationship between varicella, high ambient air temperature and clustering of students in schools,[1,2] indicated that he would review the Methods section of the HZ paper that I was preparing for

publication.[42] Glasser had previously expressed his interest in modeling HZ disease and suggested that such a model could be confirmed through data collected by Antelope Valley VASP. However, on the following day he wrote that the conclusions are premature, *"for which reason neither Carol [VASP Co-Principal Investigator], nor Jane [CDC Varicella Chief], will clear any manuscript on zoster for years."*[43] At this time, Glasser also rebuked me for not being a compliant "Boy Scout."

NM: How did you react?

GG: I was concerned that data and analyses regarding rising HZ rates were being suppressed, so I contacted Krause once again, requesting his feedback on whether to continue pursuing publication now or drop the issue and pursue publication in another 5 or 10 years (as implied by my superiors). Krause responded:

> Would CDC argue that Guess should never have published his study of zoster rates? Unless scientific findings are publicized, the very foundation on which further results can be based is never built. I agree that some of your speculations (also voiced by others in the field) regarding the effect of immunization on zoster may not be answered definitively for some number of years (as you point out in the current version of the manuscript), but that doesn't mean people wouldn't be interested in the most current data. Publication of your results might cause other investigators to look at the same question in different ways, making it unnecessary for the CDC to bear the full burden of future work on this issue. Especially since your results are somewhat different from those previously published by others, an inquiring scientific mind should want to understand why. Even if the hypothesis that [the unexpectedly high incidence rate of shingles] is due to vaccination is wrong, the results raise interesting questions about variability of zoster rates which could be very important in interpreting past and future studies. However, even if they have full legal control of the data, I would hope the CDC doesn't want to be in a position where they are preventing publication without even reading the manuscript. (Some pharmaceutical companies have been severely criticized for over-enforcing these types of agreements.) *This would create the impression that they are trying to manipulate the scientific data to prevent publication of data that could adversely influence immunization rates, regardless of the potential public health consequences* [emphasis added].[44]

NM: Dr. Krause seemed supportive of your dilemma. How did events proceed?

GG: On May 9, 2001 during a VASP conference call between Seward and VASP staff, I learned that my HZ manuscripts were in the process of being reviewed. However, the following day, when I asked Teresa Maupin for permission to phone-interview ten individuals who had experienced recurrence of shingles in the Antelope Valley (to see if the cases had involved any pre-existing conditions that made them more susceptible to repeated episodes of shingles), I was instructed not to contact them—and later, in 2002, *not to pursue any further HZ studies.*

NM: That must have been disappointing.

GG: By the end of December 2001, I had analyzed two complete years of HZ data. Case reports among adults showed a statistically significant increase of 28.5%.[11] Rates among children with a history of varicella were unusually high, approaching the rate typical of older adults, while the rate among vaccinated children was low as expected and served as a control indicating that cases of HZ were not being misdiagnosed or over-diagnosed. I also worked on determining the increased costs associated with a higher incidence of HZ in adults. *These additional costs, such as excess hospitalizations for pain and suffering, are a direct deleterious consequence of the universal varicella vaccination program which had reduced opportunities for natural, periodic exogenous boosts to immunity.*[16]

NM: Did your papers get published?

GG: By October 2002, 17 months had passed with no word regarding any progress on my HZ manuscripts that were supposedly under review. Nearly three years of HZ incidence data had been collected and it was now apparent that Glasser was correct when he asserted that the CDC would not clear for publication "any manuscript on zoster for years." And it seemed especially unlikely for any manuscript to be approved if the findings showed evidence of deleterious effects associated with the universal varicella vaccination program. It had now become unmistakable to me that VASP "research" outcomes were being driven by the CDC, VASP's sponsor. Not desiring to be a participant in what I perceived was research fraud, I resigned on October 18, 2002.

NM: Did you provide a reason for your resignation?

GG: I 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."

NM: I commend you for your integrity.

GG: Now that I was free from CDC/VASP sponsor bias, I felt a moral obligation to publish all of the varicella and HZ data I had analyzed.[12-20] Since VASP was funded by the CDC, the data collected by VASP was available to any citizen through the Freedom of Information Act.[11] Upon finalizing several papers for publication, I contacted VASP and CDC to determine whether those associated with VASP wanted to be recognized as co-authors.

NM: As a professional courtesy?

GG: Yes, but on April 10, 2003, I received from the Los Angeles County Legal Department a notification to "cease and desist" in any effort to publish or disseminate any information gathered as part of my employment with VASP (Letter 1). Consequently, I retained an attorney, M. Gayle Askren, whose reply seemed to resolve any legal issues (Letter 2). Subsequently, three of my studies were published in the October 1, 2003 issue of *Vaccine*, a well-respected European medical journal.[12-14]

NM: Congratulations. I summarized some of your published papers in my book, *Miller's Review of Critical Vaccine Studies*.[45] Did you experience any other obstacles after your papers were published?

GG: Following publication of these three papers, I was contacted by Paul W. Taylor, Senior Publishing Editor for Elsevier, the large European publisher that owns the journal *Vaccine*. He was concerned about ownership of the data in my recently published papers because the CDC was claiming it was confidential and that I had no right to the data in the studies. I faxed Taylor a copy of my attorney's letter to the Los Angeles County Legal Department, and since there was no legal reply by mid-April 2003, my lawyer and I considered this matter to be resolved. However, another one of my studies[16] that modeled additional costs associated with the universal varicella vaccination program due to the increased rates of HZ was postponed for an entire year from appearing in the print edition of *Vaccine* after Elsevier received a complaint from the CDC. Resolution of this delay required intervention by my attorney.

NM: Do you have other examples of data suppression?

GG: Ideally, the same population-based, active surveillance data should be used to compute and compare HZ incidence rates both pre- and post-varicella vaccine licensure. Unfortunately, such pre-licensure (prior to 1995) and early post-licensure (1995-1999) HZ surveillance data were unavailable. There were, however, three "surrogate" HZ incidence rates available—two from historical studies in other populations—Hope-Simpson[35] and Donahue *et al.*[37]—and one from a VASP-sponsored survey conducted among parents of middle-school students aged 10 to 14 years within the Antelope Valley population.[12] Herpes zoster incidence rates in the VASP-sponsored study were remarkably consistent with those reported in the Hope-Simpson and Donahue studies (Table 1).

NM: So, you had three studies with similar findings on the true incidence rate of shingles among children during the time period prior to the introduction of the chickenpox vaccine. Is that correct?

GG: Yes. Three methodologically different studies, conducted in dissimilar populations, during different pre-varicella vaccine time periods, reported nearly identical HZ incidence rates among individuals aged <20 years. Despite limitations inherent to the VASP-sponsored survey—which investigated 1) susceptibility to varicella, and 2) HZ incidence rates—it reflected the socio-economic and racial balance of the Antelope Valley population and appears to have accurately captured the true HZ incidence rate during the pre-varicella vaccine licensure years. Yet, while my analysis of varicella susceptibility among adolescents was accepted, approved, and presented at a CDC conference,[10] *the analysis of HZ incidence rates in the period prior to varicella vaccine licensure was deleted in its entirety and not included in the VASP Annual Report to the CDC.*

NM: It appears as though the CDC was not interested in publicizing preliminary deleterious data on shingles rates. Were there other experts in the field who realized what was happening?

GG: Yes. In 2002, Brisson and Edmunds, infectious disease experts associated with the Immunization Division of the Public Health Laboratory Service Communicable Disease Surveillance Centre in London, wrote a letter to the editor of *JAMA*[46] in which they criticized Seward, the CDC Varicella Chief, and her colleagues, for reporting that the incidence of varicella in the United States declined markedly following the introduction of varicella vaccination *without also discussing how this decline "might lead to a significantly increased incidence of HZ over the next 50 years.... Seward et al. report only half the story: trends in the annual age-specific incidence of HZ should be presented alongside the varicella data to show the full impact of the vaccination program on varicella-zoster virus disease."*

NM: The published paper by Seward and colleagues that Brisson and Edmunds were highly critical of is the same paper that you disapproved of (prior to publication) in your correspondence with Dr. Seward and Teresa Maupin. Apparently other experts were aware that the CDC was promoting *benefits* of the chickenpox vaccine program while dodging a discussion of potential *detriments* associated with the program. Did the CDC respond to Brisson and Edmunds' letter?

GG: Seward replied to their letter citing two CDC-funded sites—Massachusetts Department of Public Health (MDPH) and Group Health Cooperative (GHC) in Seattle, Washington—that were monitoring HZ incidence rates. She claimed: "To date, no increase in HZ is evident in any age group in either site."[47] This premature assessment was also disseminated by Seward during the symposium on varicella-zoster virus at

the 42nd Interscience Conference on AntiMicrobial Agents and Chemotherapy (in San Diego on September 30, 2002),[48] in a personal communication published in the Australian journal, *Communicable Diseases Intelligence*,[49] and reported by Yih *et al.*[50] at the 37th National Immunization Conference of CDC on March 19, 2003. Yih, however, acknowledged that the sample size of the MDPH study was small and a larger study was needed. The MDPH survey that Seward cited consisted of just 4,916 and 3,123 individuals aged 1-19, in years 1999 and 2000 respectively—for a total of 8,039 person-years of observation data. *Hence, the small sample size and limited observation time yielded a study design with insufficient statistical power to detect changes in age-specific HZ incidence rates.*[50]

NM: The CDC's Varicella Chief should have known this was an inadequate study as the basis for her claim that shingles rates were not increasing.

GG: The other study cited by Seward (GHC)[51] was conducted too early in a population where varicella vaccine uptake had not become sufficiently widespread to impact adult HZ incidence rates.[52] It did, however, report a 67% increase in HZ incidence rates among unvaccinated children aged <10 years—from 87 cases/100,000 person-years in 1996 to 145 cases/100,000 person-years in 2002.[51] Vaccination rates in the Seattle population cohort comprising GHC were lower than the national average. In fact, according to Jumaan *et al.*,[51] "few children (aged 1-9 years) had been vaccinated during 1996 and 1997." CDC authors acknowledged, *"The study may have been conducted too early to detect an increase attributed to decrease in exposure to varicella."*

NM: So, the CDC cited the GHC study to support a claim that no increase in shingles had been observed when the study was conducted in a population with lower than average uptake of the chickenpox vaccine. If they really wanted an answer, they could have conducted the study in another community where chickenpox vaccination was widespread. Weren't you also gathering shingles data at VASP?

GG: Yes. In contrast to the small sample size and limited observation time (i.e., insufficient statistical power) of the MDPH survey,[50] Antelope Valley VASP's study population included 118,685 individuals aged 1-19 in years 2000 and 2001, respectively[11]—for a total of 237,370 person-years of observation data. Thus, Antelope Valley VASP had an observation time that was nearly 30-fold greater (237,370/8,039) than that of the MDPH study whose conclusion was publicized by Seward and colleagues.[47-49]

NM: It seems like the CDC selectively chose which data to promote. How did the other study that the CDC cited compare with the Antelope Valley VASP data?

GG: In contrast to the GHC study which was conducted in a population with slow varicella vaccine uptake (and therefore too early to detect an increase in HZ incidence rates), Antelope Valley VASP had an early startup and rapid uptake in varicella vaccination. By 1999, just four years post-licensure, varicella incidence had already declined by 80% and varicella no longer displayed its characteristic seasonal incidence.

NM: So the chickenpox vaccine was effective at reducing the incidence of chickenpox. Now your theory about the importance of exogenous boosts to immunity—Hope-Simpson's hypothesis—may be confirmed if shingles rates rise.

GG: Unlike the MDPH and GHC studies, meaningful data and conclusions could be drawn from VASP's HZ surveillance data. For example, from 2000 to 2001, HZ cases reported to VASP either maintained or increased in every adult 10-year age category (Table 2). There was a statistically significant 28.5% increase in HZ case reports in 2001 compared with case reports in 2000 among adults aged 20 to 69 years (paired t-test: $P < 0.042$, $t=2.95$, $df=4$). In addition, the true ascertainment-corrected HZ incidence rate among children aged <10 years with a history of wild-type varicella was 484 cases/100,000 person-years for cumulative years 2000-2001 (Table 3)—3.6-fold higher than the pre-licensure rate of 133 cases/100,000 person-years, as reported by both Goldman from the VASP-sponsored survey[12] and Donahue *et al.*[37] At the same time, the HZ incidence rate among vaccinated children was approximately 30 cases/100,000 person-years which served as a control that cases of HZ were not being over-diagnosed.

NM: So, as chickenpox became less prevalent due to widespread vaccination, individuals who previously contracted chickenpox had fewer opportunities to gain natural boosts to their immunity and the dormant varicella virus reactivated as shingles. VASP's own CDC-sponsored study confirmed these statistically significant increases.

GG: Yes. Why would CDC/VASP promote invalid conclusions from a study with insufficient statistical power (30-fold less observation time) and refer to a study in a population too early to observe an impact of varicella vaccination on adult HZ incidence? Why would they ignore the unusually high HZ incidence rate reported by VASP among children aged <10 which was approaching the rate typical of older adults?

NM: It appears as though CDC wanted to highlight positive aspects of the varicella vaccination program while other data suggesting negative or deleterious findings were minimized, suppressed or disallowed.

GG: Clearly, *preliminary HZ data from CDC-sponsored VASP—rather than preliminary and misleading data from MDPH and GHC—should have been discussed in scientific papers and at international conferences* where scientists and policymakers could have planned additional studies to determine whether the preliminary results and conclusions from Antelope Valley VASP were generalizable to other populations where universal varicella vaccination had been implemented.

NM: How were you able to determine the true rates of shingles in vaccinated versus unvaccinated populations?

GG: After I resigned in October 2002, three of my papers were peer-reviewed and published in the journal *Vaccine.*[12-14] In September 2004, the CDC published a response to the three papers and was especially critical of the way in which I calculated HZ incidence rates among children.[50] However, to properly calculate HZ incidence *in a community with moderate varicella vaccination coverage* required a different methodology than the approach utilized in historical studies conducted prior to implementation of the universal varicella vaccination program. Those studies simply reported crude incidence rates by combining all children into a single cohort. This was an acceptable approach during the pre-varicella vaccine period. However, after the vaccine was licensed in 1995 and vaccine coverage rates rapidly increased in subsequent years, calculation of a crude (or population) rate was no longer an acceptable method for tracking trends in HZ incidence. Thus, I implemented an approach that stratified children into two separate cohorts: 1) those who received the varicella vaccine, and 2) unvaccinated children who had previously contracted wild-type varicella.[15] In this way, the diverse HZ incidence rates could be separately tracked in each of these distinct cohorts.

NM: So, before the chickenpox vaccine was introduced, it was acceptable to combine all children of the same age into one group to calculate the incidence of shingles. However, after the chickenpox vaccine was licensed in 1995, shingles rates had to be calculated separately in children that had received the vaccine and in unvaccinated children who had previously contracted chickenpox naturally.

GG: Yes. By 2000, with approximately 50% of the child population vaccinated, opportunities for unvaccinated children with a history of varicella to gain exogenous boosts to their immunity were greatly diminished. The incidence of HZ in this group of children would be much higher than HZ rates in vaccinated children—*and greater than HZ rates during the pre-vaccine era.* Yet, even after the varicella vaccine program matured (from 2000-2002), the CDC advocated the calculation of a single *crude* HZ incidence rate among children aged <10 years.[53] The CDC/VASP's fundamental approach was to combine into a single cohort 1) vaccinated children, and 2) unvaccinated children who had previously contracted wild-type varicella. This approach yielded a single mean HZ incidence rate of a bimodal distribution. This mean rate did not represent either of the two widely divergent HZ incidence rates. More concerning, *this had the effect of concealing the importance of exogenous boosts while masking a significantly higher HZ incidence rate (post-varicella vaccine licensure versus pre-licensure) in children with a history of varicella.*

NM: You've been able to show that the universal chickenpox vaccination program reduced cases of chickenpox but this created fewer opportunities for people who had previously contracted chickenpox to have their immunity boosted through contact with the circulating virus, making them more vulnerable to developing a case of shingles. Has the loss of these exogenous exposures to the natural (or wild) chickenpox virus caused any other undesirable effects?

GG: In 2004, CDC published a study by Seward *et al.* on the contagiousness of varicella within households, but reported only the mean accumulative varicella vaccine efficacy of 78.9% (95% C.I., 69.7% to 85.3%) during 1997-2001 stating that there was no statistically significant difference in efficacy at the 95% confidence level when the analysis was stratified by year.[54] However, this mean efficacy of 78.9% over five years masked a >10% annual drop-off in efficacy, from 96% in 1999 to 74% in 2001—which, while not significant at the 95% confidence level (z = 1.96), was significant at the 94% confidence level (z = 1.88). Further double-digit annual declines in vaccine efficacy in 2002 and thereafter were statistically significant.

NM: The chickenpox vaccine was losing its efficacy?

GG: Yes. Table 4 shows the "honeymoon" effect during 1997-1999 where vaccine efficacy increased from 87% to 96%, augmented due to vaccinees receiving exogenous exposures (natural immune boosts) from children infected with wild-type varicella (i.e., contagious children shedding varicella-zoster virus). This augmentation of vaccine efficacy would only occur during the early years of the universal varicella vaccine program as varicella remained endemic, constantly circulating in the environment. However, as more children were vaccinated and the widespread circulation of wild-type varicella declined, exogenous exposures became rare in 2000 and beyond. Single-dose vaccine efficacy plummeted, causing increased cases of breakthrough varicella (outbreaks of chickenpox in varicella-vaccinated people). Apparently, exogenous exposures to wild-type varicella not only 1) subclinically boosted cell-mediated immunity to postpone or prevent the reactivation of varicella-zoster virus as HZ in people who had previously contracted varicella (as discussed earlier), but they also 2) augmented efficacy of the varicella vaccine. *Ironically, the "success" of the varicella vaccine at reducing cases of wild-type varicella contributed to the failure of the single-dose vaccine to maintain adequate efficacy to prevent varicella in vaccinated individuals.*

NM: How did the industry respond to this finding?

GG: In 2006, a booster dose of the varicella vaccine was recommended for children aged 4 to 6 years.

NM: Did that solve the problem? Do you think that more chickenpox booster doses will be necessary in the future?

GG: Even the two-dose protocol has been reported to show waning effectiveness. Understanding the significant role that exogenous exposures played in inhibiting reactivation of varicella-zoster virus as HZ logically implies that a third and/or fourth varicella vaccine booster dose may be recommended by the CDC as declines in anti-varicella-zoster virus antibodies continue to occur each successive year following administration of the varicella vaccine (ultimately resulting in vaccinees becoming seronegative, that is, no longer able to maintain sufficient IgG-specific antibodies to protect against varicella or inhibit reactivation of HZ). In Italy, a recent study among individuals who received two doses of the varicella vaccine reported an estimated loss of anti-varicella IgG in 50% of the study group after nine years. The authors suggested a third dose of vaccine to avoid the risk of future varicella outbreaks.[55] Another recent study in a school population in China concluded, "Moderate two-dose varicella vaccine coverage was insufficient to prevent a varicella outbreak." This study also found that "two-dose recipients with breakthrough varicella are contagious."[56]

NM: Let's shift gears and talk more specifically about epidemiological studies that may provide false information when improper methodologies are utilized.

GG: The reported incidence rates in most epidemiological studies (including active surveillance) are extremely poor, missing up to 90% of the cases, with a high degree of variation.[57-60] The unadjusted rates are, at best, lower-bound estimates of the true population rates. Therefore, the options are 1) to report raw varicella and HZ cases, from which population rates are indeterminate, 2) attempt to count every case, which is expensive and slow, or 3) utilize capture-recapture, which can be a reasonably accurate, quick and inexpensive approach.

NM: Capture-recapture sampling is increasingly being used in epidemiological studies to determine reporting completeness of data. What prompted you to consider this and what did your analyses show?

GG: I attended a seminar conducted at the CDC that promoted the use of capture-recapture methods. VASP Co-Principal Investigator, Dr. Carol Peterson, had me perform numerous capture-recapture analyses using various combinations of ages and years of study. Capture-recapture consistently demonstrated 50% reporting completeness (ranging from 43% to 62%) over all child and adolescent age categories and years (2000-2001). In a study published in *JAMA*, CDC/VASP utilized my capture-recapture analysis to demonstrate that decreases in varicella incidence were not the result of a reduction in the level of reporting completeness.[8] Since the same VASP sites that reported varicella also reported cases of HZ, it was expected that the underreporting for both would be the same, and capture-recapture analysis confirmed that hypothesis. Yet, the CDC Varicella Chief, Seward, was critical of my HZ incidence rate estimates using capture-recapture since the number of HZ cases reported to VASP were considerably less than the number of reported varicella cases. On this issue, Tilling clarifies that a well-designed, incomplete disease registry (or ascertainment source) may provide a more accurate, unbiased estimate of incidence than a nearly complete accumulation of cases which fails to identify specific population groups.[61] However, because CDC/VASP

resisted application of capture-recapture methods to adjust for underreporting of HZ cases, VASP incidence rates based on the raw counts of cases *were half the true population rates.*

NM: So, the CDC selectively utilized your capture-recapture analyses to confirm that the chickenpox vaccine was reducing the incidence of chickenpox but they rejected your capture-recapture analysis when it revealed that the incidence of shingles was underestimated. They used *adjusted* rates when they accentuated vaccine program benefits but used *unadjusted* rates to conceal undesirable findings when reporting shingles incidence rates.

GG: Yes. In 2009 (14 years after varicella vaccine licensure), when the CDC finally published age-specific HZ incidence rates among children and adolescents annually for 2000 through 2006, CDC and VASP authors compared VASP *unadjusted* HZ incidence rates to rates reported in other studies using methodology with more exhaustive case collection.[62,63] Such comparisons were problematic and misleading. Since application of capture-recapture indicated a 50% under reporting of HZ cases to VASP,[13,14] *ascertainment-corrected age-specific HZ incidence rates among children aged 1-9 years and adolescents aged 10-19 years were two-fold higher than the CDC's published unadjusted rates.*

NM: So, the CDC was publishing unadjusted data that was misleading. How did this influence other scientists who trusted CDC data?

GG: The CDC's promotion of *unadjusted* age-specific HZ incidence rates, rather than ascertainment-corrected rates, created an unfortunate cascading effect in subsequent publications by other researchers (who presumed CDC data were reliable), resulting in wide variability in published age-specific HZ incidence rates. Early cumulative unadjusted HZ incidence rates that I analyzed and reported[17] for 2000-2003 were eventually corroborated by additional longitudinal VASP data for 2000-2006 that were later analyzed and reported by CDC.[62,63] There were no statistically significant differences in the unadjusted rates reported in both analyses (Table 5).

NM: Nearly twenty years have passed since you resigned from your work with the CDC-funded Varicella Active Surveillance Project. Have other studies confirmed your findings?

GG: Yes. For example, a study by Yawn *et al.*, sponsored by the Mayo Clinic, utilized data from the Rochester Epidemiology Project (REP) and found a 5.6% average annual increase in HZ incidence (during the early post-varicella vaccine period) among adults aged ≥22 years.[64] HZ incidence increased significantly, from 320 (95% C.I. 290-350) to 410 (95% C.I. 380-440) cases/100,000 person-years during 1996-2001. This study recognized that "...vaccination may reduce opportunities for varicella-zoster virus immunity boosting from exposure to natural varicella, leading to...increased incidence of HZ in older adults."[64]

NM: Have other studies contradicted your findings?

GG: Yes. Merck, the varicella vaccine manufacturer, sponsored a retrospective study (Wolfson *et al.*)[65] of HZ incidence rates during the period 1991-2016 that concluded: "The annual incidence of HZ in adults increased at approximately the same rate...in the years before and after childhood varicella vaccination took effect." However, this study has several weaknesses or limitations that create uncertainty regarding the authors' conclusion. For example, the study authors acknowledged that HZ incidence rates during the pre-

vaccine period from 1991-1995 were estimates rather than actual rates, and the MarketScan databases[66] that were utilized for the study did not reflect the true HZ incidence rates of the population.

NM: I'm not surprised that a study sponsored by the chickenpox vaccine manufacturer found that their vaccine did not cause increased rates of shingles.

GG: In 2016, a CDC-sponsored study by Kawai *et al.*[67] used the same REP data utilized by Yawn *et al.* and found that there was "no change in the rate of increase before versus after the introduction of the varicella vaccination program." However, Kawai *et al.* failed to show an increasing trend because *widely divergent HZ rates between two distinct cohorts—vaccinated and unvaccinated populations—were combined in a misleading and unscientific methodology to effectively mask the increase in adult HZ incidence rates.*

NM: So, a study sponsored by the Mayo Clinic reported an annual increase in shingles incidence that was higher than the pre-licensure rates—which supported the increasing trend that you reported from VASP (although the Mayo Clinic's rate was of a lesser magnitude)—while a CDC-sponsored study using the same database contradicted those findings.

GG: Yes.

NM: Since 1995, the chickenpox vaccine was recommended by the CDC for universal use in the United States. Thus, if CDC data were to show evidence that it causes deleterious effects (i.e., a negative cost/benefit ratio), the agency would lose credibility. I wonder if this influenced or biased their decisions.

GG: Perhaps, but whatever hidden agendas or unknown motives might have existed, my concern was simply to report the surveillance data as accurately and objectively as possible.

NM: Of course. Were there other studies that contradicted your findings?

GG: Yes. In 2018 and 2019, several CDC-sponsored studies[68-71] reported a constant increase in adult HZ incidence that remained unchanged in the periods before and after varicella vaccine licensure. These studies extracted data from large administrative databases that were subject to the same confounders and limitations previously described for MarketScan. Clearly, multiple confounders and methodological limitations in CDC-sponsored retrospective studies of HZ incidence rates—and obfuscation of deleterious data—have prolonged the specious controversy regarding the well-documented significance of exogenous exposures to inhibit reactivation of the varicella-zoster virus as HZ. I discuss the importance of exogenous exposures in my most recent paper as well.[72] (See Figure 1 for additional details regarding the Merck and CDC studies.)

NM: In 1995, Japanese scientists (Terada *et al.*)[28] found that pediatricians have enhanced protection against shingles when compared to the general population, most likely due to periodic re-exposure to children with chickenpox. However, 30 years earlier Dr. Hope-Simpson was the first to postulate the existence of this relationship. Would you like to speak about that?

GG: Hope-Simpson's 1965 hypothesis was that age-specific HZ incidence rates are dependent on the frequency of each cohort's exposure to individuals shedding wild-type varicella-zoster virus.

NM: Did your work with the CDC-sponsored VASP confirm Dr. Hope-Simpson's hypothesis?

GG: The universal varicella vaccination program provided suitable conditions in the Antelope Valley population where the CDC-sponsored VASP gathered preliminary data[11] (analyzed by me), supporting Hope-Simpson's hypothesis.[35]

NM: How soon were you able to validate Hope-Simpson's hypothesis and how would this impact the cost/benefit analysis of the universal varicella vaccination program?

GG: By the end of 2000, just five years after universal varicella vaccination was initiated and widespread vaccine coverage was achieved (among nearly 50% of children aged <10 years), varicella incidence in the Antelope Valley region no longer displayed its characteristic seasonality and exogenous exposures became rare. By 2001, preliminary, quantitative evidence began accumulating in support of the Hope-Simpson hypothesis. Despite 80% declines in varicella cases and associated lower medical costs, and the fact that the overall childhood HZ incidence rate would eventually decline below rates reported in historical pre-licensure studies, *these positive developments are insufficient to offset decades-long post-licensure HZ incidence rate increases among adults, who experience greater severity of disease than children.*

NM: Do other studies confirm Hope-Simpson's hypothesis?

GG: Four studies among adults found statistically significant increases in HZ incidence rates,[11,64,73,74] supporting Hope-Simpson's exogenous boosting hypothesis. Annual increases ranged from 5.6% (using retrospective data from large administrative databases which underestimated true population rates) to 28.5%, depending upon study methodology and how quickly and widespread varicella vaccine uptake occurred in the study population. Four studies conducted among children and adolescents[12,51,62,75] also found statistically significant increases in HZ incidence rates early post-licensure. Annual HZ incidence rate increases ranged from 10.8% to 45.2%. Annual increases in HZ incidence rates during the post-varicella vaccine period were of greater magnitude than those reported in the pre-vaccine era. More recent studies have also examined the significance of exogenous boosting in relation to the Hope-Simpson hypothesis.[76-79]

NM: There are ethical issues associated with introducing a vaccination program that could advance the health of one population group (reduced cases of chickenpox in children) at the expense of another (increased cases of shingles in adults).[80] Considering your nearly eight-year relationship with the CDC, do you believe it's a trustworthy public health agency?

GG: Dr. Julie Gerberding served as Director of the CDC from 2002 until her resignation in 2009 to become president of Merck's vaccine division. I do not know whether conflicts of interest between CDC and the varicella vaccine manufacturer played a role in concealing the importance of exogenous boosting and censorship of deleterious outcomes associated with the universal varicella vaccination program, especially concerning increasing HZ incidence rates. However, due to blatant biases such as those described in this interview, CDC/VASP seemed to serve as a commercial enterprise marketing a product rather than as an impartial national public health agency reporting on the true impact that universal varicella vaccination had on the U.S. population.

NM: Do you have any concluding comments?

GG: The U.S. universal varicella vaccination program reduced cases of chickenpox but also caused a significant increase in adult HZ incidence rates. Excess medical costs for pain and suffering are a direct

deleterious consequence of the program. The CDC reported all positive findings while negative data were either suppressed or misrepresented to make unfavorable outcomes appear less concerning than they actually were. Several acts of scientific misconduct and/or malfeasance by the CDC (Figure 2) perpetuated a false narrative regarding the role that universal varicella vaccination played in reducing exposures to wild-type varicella, which provide natural immune boosts that 1) enhance varicella vaccine efficacy to prevent chickenpox in vaccinated people, and 2) inhibit reactivation of the varicella-zoster virus as HZ in unvaccinated individuals with a history of natural chickenpox. When public health agencies fail to remain impartial—whether inadvertently or by design—health authorities lose their credibility, our confidence in the veracity of scientific research is diminished, and large populations may be exposed to increased rates of adverse health consequences. Finding ways to improve vaccine safety and increase CDC accountability must be top priorities.

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Availability of Data and Materials: The datasets supporting the conclusions of this interview, collected via the Antelope Valley Varicella Active Surveillance Project, are available through a Freedom of Information Act (FOIA) request to Centers for Disease Control and Prevention (CDC, Atlanta, GA) for the Antelope Valley Varicella Active Surveillance Project (VASP) Summary Reports provided by the Los Angeles County Department of Health Services; Cooperative Agreement No. U66/CCU911165-10.

Abbreviations
CDC: Centers for Disease Control and Prevention
GHC: Group Health Cooperative
HZ: herpes zoster (shingles)
MDPH: Massachusetts Department of Public Health
VASP: Varicella Active Surveillance Project

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Letter 1: Goldman is the recipient of a "Cease and Desist" notice

Notice to Research Analyst to "cease and desist" publication

COUNTY OF LOS ANGELES
OFFICE OF THE COUNTY COUNSEL
648 KENNETH HAHN HALL OF ADMINISTRATION
500 WEST TEMPLE STREET
LOS ANGELES, CALIFORNIA 90012-2713

LLOYD W. PELLMAN
April 10, 2003
TDD (213) 633-0901
TELEPHONE (213) 974-0901

VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Gary S. Goldman, Ph.D.

RE: Varicella Active Surveillance Project

Dear Mr. Goldman:

This office represents the County of Los Angeles Acute Communicable Disease Control Unit. It has come to the attention of that office that you have….

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.

Letter 2: Goldman responds to "Cease and Desist" notice

Attorney for Goldman responds to "cease and desist" notice

ASKREN LAW FIRM
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M. Gayle Askren
Attorney at Law
In Practice Since 1972

Refer to Date: April 17, 2003

FACSIMILE TO 619-687-4745 AND FIRST CLASS MAIL

Robert E. Ragland, Senior Deputy County Counsel
County of Los Angeles, Office of the County Counsel
500 West Temple Street, Room 648
Los Angeles, California 90012-2713

Re: Varicella Active Surveillance Report: Our Client, Gary S. Goldman, Ph.D.

Dear Mr. Ragland:

This office has been retained to represent Gary S. Goldman, Ph.D., in the matter now pending in your office respecting his right to publish certain materials in the *New England Journal of Medicine* or elsewhere. He acknowledges your letter of April 10, 2003, in which your client communicated its notice that he cease and desist any efforts to publish or disseminate. Dr. Goldman has no intention to cease or to desist his efforts to communicate facts openly to the public and in the fundamental interest of public safety. Any attempted action on the part of your client to exercise any prior restraint is legally objectionable and will be vigorously defended.

In addition I have counseled Dr. Goldman that (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.

...In addition, the restrictions suggested upon Dr. Goldman by your letter are so vague, overbroad, and ambiguous as to be unenforceable.

For at least the forgoing reasons, your client's position at this time in this matter is not well taken and would be soundly rebutted by Dr. Goldman if necessary.

Dr. Goldman requests that your response to this reply be in writing and be delivered in the same expeditious manner as this letter.

Sincerely,
ASKREN LAW FIRM
M. Gayle Askren, Esq.

Table 1. HZ incidence rates (cases/100,000 person-years) among individuals with a history of wild-type varicella aged <20 years in the pre- and early post-varicella vaccine licensure periods.

Study	Cumulative years	Age (years)	Observation time (p-y)	HZ incidence rate (95% C.I.)
VASP-sponsored[12]	1986-2000	<15	29,249	**133** (95-182)
Hope-Simpson[35*]	1947-1962	10-19	7,280	**138** (74-255)
Donahue *et al.*[37]	1990-1992	<14	36,842	**133** (98-176)

[*]Hope-Simpson computed crude HZ incidence rates that included observation time among individuals who never had varicella. However, since few children in the 10-19 year age-category remain susceptible to varicella, the *true* and *crude* incidence rates are similar.

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Table 2. Adult HZ case reports stratified by 10-year age categories, VASP, 2000-2001

Adult age category[a] (years)

Year of surveillance	20-29	30-39	40-49	50-59	60-69	Total
2000	10	20	50	43	35	158
2001	19	27	50	62	45	203

[a]Elderly adults, aged 70 years and older, both prior to and following varicella vaccine licensure, had few opportunities for periodic exogenous boosting, and therefore the HZ incidence rate among elderly adults is less sensitive to effects of widespread varicella vaccine coverage. The sedentary lifestyle of aged adults is in contrast to younger adults who are (1) more active in the community and (2) may engage frequently in activities involving school-age children.

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Table 3. Unadjusted and ascertainment-corrected HZ incidence rates among children with a history of wild-type varicella, VASP 2000 & 2001

Year	Age (years)	Observation time (p-y)	Unadjusted HZ incidence rate (95% C.I.)	Ascertainment-corrected HZ incidence rate
2000	<10	16,127	236 (167-323)	472
2001	<10	10,751	251 (169-371)	502
Cumulative (2000-2001)	<10	26,878	242 (186-308)	484

Table 4. Annual efficacy of single-dose varicella vaccine in households, VASP 1997-2001 stratified by year[17] and CDC-reported mean efficacy[54]

Year	Goldman-reported[17] Vaccine efficacy percentage[a] (95% CI)	CDC-reported[51] mean efficacy percentage[b] (95% CI)
1997[c]	87 (75-93)	
1998	94 (83-98)	
1999	96 (83-99)	78.9 (69.7-85.3)
2000[d]	86 (74-92)	
2001	74 (58-94)	

[a]Efficacy based on household contacts aged <20 years.[17]
[b]Efficacy based on household contacts aged 1-14 years, but neglected transmission resulting from vaccinated (breakthrough) primary cases which increased in proportion from 3.4% in 1997 to 32.9% in 2001.[54]
[c]37.9% varicella vaccination coverage among children aged 19-35 months
[d]82.1% varicella vaccination coverage among children aged 19-35 months

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Table 5. Comparison of cumulative HZ incidence rates (cases/100,000 p-y) among children and adolescents reported by CDC/VASP[62,63] and Goldman.[17]

Varicella exposure History Age in years	CDC-reported[62,63] VASP cumulative 2000-2006 HZ incidence rate Unadjusted (95% CI)[a]	Goldman-reported[17]	
		VASP cumulative 2000-2003 HZ incidence rate Unadjusted (95% CI)[a]	Ascertainment-corrected[b]
Vaccinated children, 1-9	19 (15 - 25)	13.8[c] (9 - 21)	27.6
Children w natural disease, 1-9	239 (193 - 295)	223[d] (180 - 273)	446
Children w natural disease, 10-19	69 (61 - 77)	61 (51 - 72)	122

[a]CDC/VASP authors' 2000-2006 unadjusted HZ incidence rates (based on raw counts of HZ case reports) confirm Goldman's 2000-2003 findings.
[b]Capture-recapture estimated 50% reporting completeness.
[c]Based on 21 cases reported during an observation time of 152,250 p-y.
[d]Based on 94 cases reported during an observation time of 42,096 p-y.

Figure 1: Additional details regarding the Merck and CDC studies

More than twenty years after the varicella vaccine was licensed, Merck—the varicella vaccine manufacturer—sponsored a retrospective study (Wolfson *et al.*)[65] of HZ incidence rates during the period 1991-2016 that concluded: "The annual incidence of HZ in adults increased at approximately the same rate...in the years before and after childhood varicella vaccination took effect." However, this study has several weaknesses or limitations that create uncertainty regarding the veracity of the authors' claim that the universal varicella vaccination program had no impact on increasing HZ incidence rates:

1) The study authors acknowledged that HZ incidence rates during the pre-vaccine period from 1991-1995 were estimates rather than actual rates.

2) The study reported that the annual incidence of HZ increased steadily "from 1991 to about 2012 in the age categories >18 years." However, excluding the estimated HZ incidence rates during the pre-vaccine period, there was a greater than 150% increase in the HZ incidence rate over a span of 17 years (1995-2012), or nearly 9% annually. This average annual increase in the HZ incidence rate during the post-vaccine period, as reported by Wolfson *et al.,*[65] is more than three times greater than the 2.5% and 2.3% average annual percentage increase reported by Donahue *et al.*[37] and Ragozzino *et al.*[38] during the pre-licensure period.

3) The MarketScan databases[66] that were utilized for the study did not reflect the true HZ incidence rates of the population. IBM (2020) Watson Health, the provider of the MarketScan databases, acknowledged that the database sources were not representative of the U.S. population. Patient enrollment and health information systems at each HMO are dynamic which may impede the study of specific outcomes of HZ incidence. Other stated limitations include the use of a convenience sample (with a preference toward individuals insured by large employers) which created a homogenous rather than a random population sample. *Thus, HZ studies that utilized MarketScan databases were limited in their ability to detect true population trends.*

In 2018 and 2019, several CDC-sponsored studies[68-71] reported a constant increase in adult HZ incidence that remained unchanged in the periods before and after varicella vaccine licensure. These studies extracted data from large administrative databases that were subject to the same confounders and limitations previously described for MarketScan.

A study by Yawn *et al.* sponsored by the Mayo Clinic utilized data from the Rochester Epidemiology Project (REP) for Olmsted County, Minnesota and found a 5.6% (28%/5-year span) average annual increase in HZ incidence (during the early post-varicella vaccine period) among adults aged ≥22 years.[64] HZ incidence increased significantly, from 320 (95% C.I. 290-350) to 410 (95% C.I. 380-440) cases/100,000 p-y during 1996-2001. This study recognized that *"...vaccination may reduce opportunities for varicella-zoster virus immunity boosting from exposure to natural varicella, leading to...increased incidence of HZ in older adults."* However, a CDC-sponsored study by Kawai *et al.*, utilized the same REP database and found an increase of just 2.5% per year "after adjusting for age and sex" among individuals of all ages over a 60-year period ending in 2007.[67] This study claimed that there was "no change in the rate of increase before versus after the introduction of the varicella vaccination program." What accounted for this disparity, a greater than two-fold difference—5.6% versus 2.5%—in the average annual percentage increase in HZ incidence rates between the Mayo Clinic study and the CDC-sponsored study?

The Yawn *et al.*/Mayo Clinic study[64] considered only adults aged ≥22 years while the Kawai *et al.*/CDC study[67] reported an HZ incidence rate that represented the mean of individuals of *all* ages in the population, *including the low HZ incidence rate among varicella-vaccinated children*. By including the cohort of varicella-vaccinated children that had accumulated in Olmstead County since the varicella vaccine was licensed in 1995, Kawai *et al.* averaged the low HZ incidence rate in that expanding vaccinated cohort with the increasing HZ incidence rate in the unvaccinated adult cohort during 2000-2007,[67] thereby creating an artifact—a confounded HZ incidence rate—that appeared unchanged before and after varicella licensure. While the Mayo Clinic study captured an increasing trend in HZ incidence rates among adults during the post-varicella vaccine licensure period, Kawai *et al. did not show an increasing trend because widely divergent HZ rates between two distinct cohorts—vaccinated and unvaccinated populations—were combined in a misleading and unscientific methodology to effectively mask the increase in adult HZ incidence rates.* Clearly, multiple confounders and methodological limitations in CDC-sponsored retrospective studies of HZ incidence rates—and obfuscation of deleterious data—have prolonged the specious controversy regarding the well-documented significance of exogenous exposures to inhibit reactivation of the varicella-zoster virus as HZ.

Figure 2: Evidence of scientific misconduct and/or malfeasance by the CDC

Summary of the CDC's suppression of undesirable data

- The CDC failed to require active surveillance of HZ at the start of the universal varicella vaccination program despite prior knowledge by the FDA and Merck that "universal vaccination might result in increased rates of herpes zoster in vaccinated and unvaccinated individuals."
- The CDC would not clear for publication any of Goldman's manuscripts on HZ. After he resigned and was finalizing several papers for publication, he received a notification to "cease and desist" in any effort to publish or disseminate any information gathered as part of his employment with VASP.
- A CDC-sponsored survey provided two main findings: varicella susceptibility among adolescents and true HZ incidence rates prior to varicella vaccine licensure. Although Goldman's analysis of varicella susceptibility among adolescents was accepted, approved, and presented at a CDC conference, his analysis of true HZ incidence rates was deleted in its entirety and not included in the VASP Annual Report to the CDC.
- The CDC Chief promoted two studies—one with insufficient statistical power to detect changes in HZ incidence rates and another where uptake of varicella vaccination was slow and therefore too early to observe any effects on adult HZ incidence rates.
- The CDC disregarded VASP study data showing a statistically significant increase in HZ following universal varicella vaccination.
- The CDC failed to stratify childhood HZ incidence rates into two separate cohorts. This had the effect of concealing the importance of exogenous boosts while masking the significantly higher post-licensure HZ incidence rate in children with a history of varicella relative to vaccinated individuals and pre-licensure rates.
- Single-dose vaccine efficacy plummeted when exogenous exposures became rare in 2000 and beyond, a finding obscured by the CDC. The early success of the single-dose varicella vaccine program at reducing cases of wild-type varicella contributed to the failure of the single-dose vaccine to maintain adequate efficacy as the program matured.
- The CDC publicized *unadjusted* HZ incidence rates that merely reflected incidence of reporting to VASP, instead of utilizing ascertainment-corrected counts of reported cases that were two times higher, yielding true population rates.
- Retrospective studies sponsored by the CDC and varicella vaccine manufacturer utilized weak and inadequate data—rather than more robust data collected prospectively by VASP—to erroneously conclude that the universal varicella vaccine program had no impact on increasing HZ incidence rates.