

Nothing to Sneeze At

Flu Research Reveals Conflict-of-Interest Pandemic

by Peter Doshi

June 13, 2005

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Word Count: ~5500 (excluding notes and bibliography)

“An influenza pandemic is a global outbreak of influenza... There were three pandemics in the 20th century... 1968-69, 'Hong Kong flu,' [A (H3N2)], caused approximately 34,000 deaths in the United States.”

— CDC, “Influenza (Flu) Pandemics”¹

“I would emphasize that flu is a serious disease. 36,000 people on average die even in a year that is not a pandemic in this country.”

— Dr. Julie Gerberding, Director, CDC²

The Flu Vaccine Crisis of 2004

Last year's flu season got off to a strange start. Typically, as October and November roll in, one hears stories of the flu season's first victims plus some dire predictions for the months ahead. But this year something different happened.

News reports announced that America's second largest flu vaccine supplier, Chiron Corporation, just had its only flu shot factory padlocked by the British government. Virtually the entire production run was suspected to be contaminated with bacteria. This meant that America would lose some 50 million doses of its vaccine supply, half of the targeted 100 million officials were counting on for the 2004-05 season.

Chiron—a name so foreign to the American psyche that President Bush incorrectly referred to it as a foreign company³—was suddenly the spark that set off a national panic. As people lined up in droves to get their flu shot, officials at the Centers for Disease Control and Prevention (CDC) reassured us there was no need for hysteria. They suggested the country could manage this crisis by rationing, giving priority to those most in need. While officials hastily drafted recommendations, experts took to the media to declare America should take steps to insure it never finds itself in this catastrophe again. Our reliance on only three companies to handle the entire US population had turned into a bitter lesson; the system needed to be changed. Chiron, for the most part, kept a low profile.

Meanwhile, the Bush administration was taking heavy hits from Democratic presidential candidate John Kerry for mishandling America's vital vaccine supply. After all, this crisis occurred on President Bush's watch.

¹ CDC (2004), “Influenza (Flu) Pandemics.”

² Comments made during a 27 August 2004 CDC press conference discussing Chiron Corporation's initial announcement of delivery delays due to contamination concerns. See Gerberding (2004).

³ See Bush (2004). It is interesting to note that President Bush also claimed “we [America] took the right action and didn't allow contaminated medicine into our country,” a false statement. In Chiron's press release of 26 August 2004, they state: “Chiron announced ... it had delivered its first 1 million doses to U.S. distributors” Chiron Press Release (2004). Later, *USA Today* confirmed from both Chiron and vaccine distributors that more than 6.5 million doses were in the U.S., something Chiron failed to publicly disclose (Appleby and Schmit, 2004).

From the outset, much information was missing from the puzzle. For example, who discovered the contamination? Chiron? The FDA? Or was it British regulators?⁴ And when was it discovered? Was anybody doing an investigation?

At the same time the CDC was trying to reassure the public the crisis could be managed, media outlets played on peoples' fears by stressing how devastating the impact of 50 million lost flu doses would be. What they failed to mention was that until last year, only 70-75 million Americans typically even received flu shots.⁵ With 56 million doses still slated to come from other manufacturers, such information might have helped allay some of the panic.

My curiosity was piqued. The media overwhelming portrayed the flu as a deadly illness for which only one reasonable response existed: vaccination. Concerned with the accuracy of such a simplistic message, I began delving into the arcane world of health statistics, and the strange relationship between our public health agencies and for-profit pharmaceutical firms.

Seventh Leading Cause of Death?

I began with what most people believe to be true: the flu is a major killer during the annual “flu season,” claiming 36,000 lives every year in America. Furthermore, the flu is known to cause complications like pneumonia which could ultimately result in death, especially for the elderly, immune suppressed and very young. For people in their mid-twenties (like me), it was more of a nuisance—an unpleasant winter sickness that lasted around a week.

The 36,000 deaths/year statistic sounds quite serious. Almost any article on the flu mentions it. If they happen to attribute it, the source is usually the CDC.

A quick check at the CDC website confirms this figure. Under a section entitled “Influenza: The Disease,” the CDC states that “Millions of people in the United States — about 5% to 20% of U.S. residents — will get influenza each year. An average of about 36,000 people per year in the United States die from influenza, and more than 200,000 have to be admitted to the hospital as a result of influenza.”⁶

Here's where things started to get strange. Elsewhere on the CDC site I learned that “influenza and pneumonia” are the seventh leading *cause* of death in America.⁷

Excuse me? Why was the flu getting bundled with pneumonia? And why are the two *together* referred to as a leading *cause* of death?

I dialed the CDC and was referred to Ken Kochanek, a statistician for the National Center for Health Statistics (NCHS), the CDC unit where such data is compiled. Kochanek happens to author many of the official publications where leading causes of death are tallied. He explained that influenza and pneumonia are “put in the same category because the World Health Organization puts them in the same category,”

⁴ Though the British Medicines and Healthcare product Regulatory Agency (MHRA) suspended Chiron's factory license, specifics remain unknown. The MHRA has only said their decision was based on “failure to comply with the requirements of Good Manufacturing Practice” (MHRA, 2004).

⁵ CDC (2003), “CDC Assessing Influenza Vaccine Now In Supply Pipeline.”

⁶ CDC (2005), “Influenza: The Disease.”

⁷ CDC (2004), “Deaths—Leading Causes.”

a convention the U.S. follows. It's as simple as that.

While this helps explain the technicality, I wanted to understand the medical rationale behind the flu/pneumonia coupling. Kochanek suggested I speak with a medical doctor for those details.

I turned to Dr. David Rosenthal, Director of Harvard University Health Services. Dr. Rosenthal explained, “People don't necessarily die, per se, of the [influenza] virus—the viremia. What they die of is a secondary pneumonia. So many of these pneumonias are not viral pneumonias, but secondary [pneumonias]. They get so debilitated from the virus—from the flu—that they develop what's called a secondary pneumonia. That's why it's the very young that are susceptible. And the very old.”

Is the flu/pneumonia relationship so strong and unique to warrant inseparability on the leading causes of death chart? Dr. Rosenthal says no. Flu is linked to pneumonia for the same reason anything that debilitates the immune system is linked to pneumonia. Even old age is linked to pneumonia. Dr. Rosenthal pointed out that suppressed immune function is a reason why the elderly disproportionately develop, and die from, pneumonia. And it doesn't stop there. Take a study published last year in the *Journal of the American Medical Association (JAMA)* which shows that people taking acid-reflux medication are four to five times more likely to develop pneumonia than those who do not take the medication.⁸ Given this increased risk, many elderly taking such medications would have a heightened chance of developing a fatal dose of pneumonia. In other words, acid-reflux drugs and pneumonia are linked.

Thus should “Pneumonia, Flu, Old Age, and Acid-Reflux Medication” become the new seventh leading cause of death? No. The selection is arbitrary, and so it makes about as much sense as bundling pneumonia with the flu.

How Many People Really Die of the Flu?

The National Vital Statistics Report (NVSR), published by the NCHS, is the bible for official government stats on such things as births, deaths, marriage, and divorce. One NVSR report I consulted was titled “Deaths: Final Data for 2001.”⁹ On page 8 of the detailed 86-page report is a *Leading Causes of Death* chart showing that now familiar category “Influenza and Pneumonia” as the seventh leading cause of death, claiming 62,034 lives in 2001. So what is the exact breakdown? A quick mental subtraction of 36,000 (flu deaths) suggests that around 26,000 people must have died from pneumonia in 2001.

But further reading shows common sense can be very misleading.

In a 4-page-long table of data called “Number of deaths from 113 selected causes by age: United States, 2001,” we find that in actuality, pneumonia claimed 61,777 of those 62,034 lives. The flu killed 257.

Officially, only 257 people died from the flu in 2001. Of those, in 239 cases, the virus was never even identified, making it impossible to say with certainty that they died from the flu. All one can say is they died with flu-like symptoms, and therefore the doctor recorded flu on the death certificate.

I wondered whether many people who get the flu and subsequently die of

⁸ Laheij RJF, Sturkenboom MCJM, Hassing R-J, et al. (2004).

⁹ See Arias (2003) for full citation.

pneumonia have their death tallied in the “pneumonia” category. That might explain why the breakdown was so uneven. No such luck. The document's technical notes specify: “In this report tabulations of cause-of-death statistics are based solely on the underlying cause of death. The underlying cause is defined by WHO as 'the disease or injury which initiated the train of events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury.’”¹⁰

So was 2001 an unusually mild season for the U.S., with fewer than one percent of expected casualties?

The official NVSR data suggest the answer might be yes, but the numbers get even more difficult to reconcile with CDC statements. Using the publicly accessible “CDC Wonder” database, I pulled up the data for influenza deaths.¹¹ Via the web, one can access historical mortality data back to 1979. Between 1979 and 2002 (the most recent year included in the database), the flu took an average 1,348 lives per year. On any particular year, the numbers varied from 257 to 3,006.¹² 2001 was thus a mild year for the flu—yet never in the past two decades had flu deaths reached even 10% of the 36,000 figure.

The CDC Media Relations office assured me they were well aware of this discrepancy and told me *both* numbers are correct. They wrote the following in their email: “I’ve included an explanation as to why the National Vital Statistics numbers are so much lower than the 36,000 number you’ve seen printed widely. Both are correct and the information below will help to clarify.”¹³ Their explanation states:

Why does the CDC estimate flu deaths at 36,000 annually when far fewer are reported through NCHS?

Typically, influenza causes death when the infection leads to severe medical complications. Most of the people who die from these complications are never tested for influenza virus infection and therefore most such deaths are never identified in death certificates as deaths caused by influenza. For example, in 2002 there were 753 influenza deaths and in 2001 there were 257 influenza deaths identified directly in death certificates in the U.S. in those years and recorded in the National Center for Health Statistics figures. CDC considers these figures to be a very substantial undercounting of the true number of deaths from influenza.

Therefore, the CDC uses indirect modeling methods to estimate the numbers of deaths associated with influenza, an approach that has been used for over 40 years. Using this approach, CDC estimates that approximately 36,000 influenza-associated deaths occur annually in the United States. This estimate is obtained by using the models to analyze NCHS underlying respiratory and circulatory deaths. The estimated 36,0000 [sic] deaths from

¹⁰ Ibid., p100.

¹¹ Flu deaths are categorized by codes ICD-9 code 487 and ICD-10 codes J10-J11.

¹² Official number of deaths due to influenza (1979-2002): 1979: 604; 1980: 2702; 1981: 3006; 1982: 727; 1983: 1431; 1984: 1096; 1985: 2054; 1986: 1838; 1987: 632; 1988: 1943; 1989: 1593; 1990: 2098; 1991: 1137; 1992: 1006; 1993: 1044; 1994: 1229; 1995: 606; 1996: 745; 1997: 720; 1998: 1724; 1999: 1665; 2000: 1765; 2001: 257; 2002: 727. Source: CDC Wonder (2005).

¹³ CDC Media Relations, personal correspondence, 2 November 2004.

influenza represents approximately 3 percent of the approximately 1.1 million underlying respiratory and circulatory deaths that occur during a year.

In other words, when the CDC actually counts flu deaths, they never pass 3,006. But when they estimate, they come up with 36,000.

Also attached to their email was a *JAMA* article from January 2003 entitled “Mortality Associated With Influenza and Respiratory Syncytial Virus in the United States.” This is the very article that is cited whenever the phrase “36,000 deaths per year” is used in CDC literature, and it is thus central to understanding the disconnect between actual mortality data and CDC estimates.

Seven CDC researchers¹⁴ authored this dense, eight-page article, and state their objective clearly: “To develop a statistical model using national mortality and viral surveillance data to estimate annual influenza—and RSV—associated deaths in the United States, by age group, virus, and influenza type and subtype.”

RSV stands for “respiratory syncytial virus.” They explain, “RSV epidemics often overlap with influenza epidemics, and RSV infections have been associated with substantial morbidity and mortality in young children and more recently in older adults.” So besides sharing some similarities in timing with the flu, RSV is not the flu. It is rather an area of growing concern for these authors who wanted to include it in their paper. For my purposes, I needed to figure out how this paper established the famous “36,000 flu deaths per year” figure.

Working my way through the document, I searched for the number “36,000.” It was a fruitless search. The corresponding number in their report is 36,155. Technically, it represents an average of estimated annual influenza-associated underlying respiratory and circulatory deaths for the 1990-1991 through 1998-1999 seasons. Just to be sure my assumption was correct, I phoned Dr. William Thompson, Ph.D., of the National Immunization Program’s Immunization Safety Branch, and principal author of the *JAMA* article. He confirmed this was indeed where the number 36,000 came from.

Why don’t people use the more precise 36,155? Just imagine this. Following the lead of the CDC, newspaper articles and TV newscasters announced that, “every year, an average of 36,155 people die from the flu.” Hardly sounding like an estimate produced from a statistical model, such a number would falsely suggest officials were averaging raw data. Most likely for this reason, a well-rounded number—36,000—was adopted and standardized.

I could not help but feel a little deceived. From organizations like the CDC, one would expect a bit more precision in their language. Rather than declaring “36,000 people die from the flu each year,” the CDC could have said, “Statistical models estimate annual influenza-associated death around 36,000 per year.” After all, we are

¹⁴ The article details author affiliations: “Influenza Branch (Drs Thompson, Cox, and Fukuda, and Mr Weintraub and Ms Brammer) and Respiratory and Enteric Viruses Branch (Drs Shay and Anderson), Division of Viral and Rickettsial Diseases, National Center for Infections Diseases, Centers for Disease Control and Prevention, Atlanta, Ga. Drs Thompson and Shay, and Mr Weintraub are now with the Immunization Safety Branch, Epidemiology and Surveillance Division, National Immunization Program [also part of the CDC]” (see Thompson, et al. 2003).

dealing with an estimate derived from mathematical formulas; the article and their email to me make that very clear. The caution with which the authors proceed at the article's outset, "...numbers of deaths attributable to influenza are difficult to estimate..." is somehow not reflected on their website, where they matter-of-factly declare: "An average of about 36,000 people per year in the United States die from influenza." This kind of statement lacks the caution and comes across as authority speaking from the vantage point of knowing the truth. On the contrary, 36,000 is no more than the latest guess about what is "difficult to estimate." Losing my faith in the CDC, I began to wonder whether the authors of the CDC website knew the difference between a fact and an opinion.

Yet this was hardly the most damning distortion that sprung from the *JAMA* article. A critical read—I did not catch it the first time around—finds that the authors are not putting forward an estimate of influenza mortality, but rather "influenza-associated" mortality.

Influenza mortality—or death from the flu—seems straightforward. But what is influenza-associated mortality?

"It's a statistical association between deaths and viral data available," explained Dr. Thompson over the phone, author of the *JAMA* study. I asked whether "associated" means it was the actual cause of death. He responded that "based on modeling, we think it's associated. I don't know that we would say that it's the underlying cause of death."

Thus the CDC is not modeling how many people died from the flu, as is commonly thought, but constructing mathematical projections to estimate the number of people who died where the flu was one of the complicating factors. And this complication could have played a minor—or major—role. Since these are projections of flu involvement where the flu was never recorded, nobody can accurately say.

Not all experts in the field readily accept the CDC's model. "We are concerned that their model was inappropriate," writes a four-author team from the Communicable Disease Surveillance Centre in London. "When designing a model to attribute causality to deaths, a reasonable initial approach would be to assume that the number of deaths due to a specific virus in any given week was proportional to the number of laboratory reports of that virus in that week."¹⁵ "Instead, [the authors of the *JAMA* article] used a Poisson model in which the number of deaths increased exponentially with the number of laboratory reports and the effects ... were multiplicative rather than additive. We do not believe that there is plausible justification for fitting such a model to these data." I, too, felt there was something fishy about that Poisson model.

The London scientists were not alone in their dissent—all of the follow-up letters published by *JAMA* criticized the model. In another letter sent in, National Institutes of Health researchers state, "We propose that rigorous demonstrations of validity and benefit precede adoption of this new modeling approach."¹⁶

The criticism was good news but troubling in its outcome. Disagreement is the bedrock of science, yet the net effect of the follow-up letters was as if they did not exist.

¹⁵ Gay, et al. (2003).

¹⁶ Simonsen, et al. (2003).

Opinion Becomes Fact

As a result of the controversial modeling approach, the size of America's annual flu epidemic nearly doubled overnight. The new CDC figure was 80% higher than their previous *de facto* estimate of 20,000 deaths/year,¹⁷ yet in the face of criticism and caution, 36,000 became America's new truth.

On January 8, 2003, coinciding with the *JAMA* publication, newspaper headlines across America screamed the news: "Flu deaths up sharply in U.S. since 1970s, largely because of aging population;"¹⁸ "Flu Deaths Surge Amid Concerns For Elderly Care --- Report Says 36,000 People Die Per Year, With 90% Of Them 65 and Over."¹⁹

These articles were the last time the 36,000 figure would be referred to as an estimate derived from a new statistical model. It was also the first time 36,000 estimated "influenza-associated deaths" would come to be incorrectly known as 36,000 "influenza deaths," a false perception that continues to this day.

Noticing the very same equating of the two terms in the material the CDC had sent me, I called them again for an explanation. I asked how they can say that "approximately 36,000 influenza-associated deaths occur annually" and at the same time claim "36,000 [sic] deaths from influenza"?

The CDC representative put me on hold to check with superiors. She came back and agreed they were different, and characterized it as a semantic error. She explained that it was a mistake, and they should both read influenza-associated.

This "semantic error" is not simply a "mistake," but a factual misrepresentation that has led to the widespread belief that the flu *kills* 36,000 people per year—a misconception that has yet to be publicly corrected.

Considering that newspapers and wire services such as *The Wall Street Journal* and *AP* announced the new 36,000 figure the same day *JAMA* published the CDC model, it appears that reporters were responding to press releases rather than reading actual source material. Not surprisingly, the media were silent later in May when *JAMA* published three peer criticisms of the new CDC model.²⁰

Still left is the question of whether the new estimate of 36,000—80% higher than the old estimate of 20,000—is any better.

The CDC's new estimate came with curious explanations. On National Public Radio's *Morning Edition* of January 8, 2003, listeners were offered this: "Fukuda [CDC researcher, and co-author of the *JAMA* article] says the increase is real and has two possible causes. One is that the number of people older than 65 is growing larger... The second possible reason is the type of virus that predominated in the 1990s. It causes more serious illness and more deaths than other flu viruses."²¹

Logic suggests reason number one does not make sense. The population aged

¹⁷ CDC (2002), "Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP)."

¹⁸ Tanner (2003).

¹⁹ Carrns (2003).

²⁰ See Gay, NJ, Andrews, NJ, Trotter, CL, et al. (2003); Glezen WP, Couch RB (2003); Simonsen L, Blackwelder WC, Reichert TA, et al. (2003).

²¹ NPR (2003), "Profile: Deaths from flu on the rise."

65 and over grew only 12% between the 1990 and 2000 censuses.²²

The second reason—that the 1990s saw more virulent strains—is also hard to grasp because there is simply no objective evidence for it. During the 1980s, the number of deaths the CDC recorded as attributable to flu came to an average of 1702. During the 1990s, just 1197. In the same time period that identified flu deaths were down, the estimated deaths went up.

I posed this seeming numerical contradiction to Dr. Thompson, the *JAMA* article's lead author.

“I'll tell you what we believe. We just believe that that data [the underlying flu deaths data] is not reliably recorded, in terms of what's recorded on the death certificate,” Thompson said.

“But are you not using that same data which you call unreliably recorded to produce your numbers?” I questioned.

“We're using it [the flu deaths] with pneumonias... we never analyze influenza alone. So by combining them we're treating it as if it's a pneumonia because the majority of influenzas and pneumonias are pneumonias... so we end up analyzing that combined category.”

I was not the only one to feel uncomfortable with the contradictory trends. “I think it is an important point to clarify for people if we're going to continue to move and collect data. We've got to be consistent,” said Dr. David Rosenthal at Harvard University Health Services. “If you say it's going down when it's really up or up when it's going down, that bothers me.”

* * *

The central conclusion drawn from the CDC model is that the flu plays a part in 36,000 deaths per year in America. The justification for such a conclusion, however, appears to mainly be the subjective belief of Dr. Thompson and his co-authors, and the motivation for it remains unclear.

The hint of a possible motivation surfaced in media reports on the day of the CDC announcement itself, when the *Associated Press* reported that “Health and Human Services Secretary Tommy Thompson said the news 'that influenza may be taking an even larger toll than we have realized' underscores the importance of flu shots, especially for older people.”²³ The CDC's new estimate led to an immediate public health judgment—that flu shots are important.

One expects government health officials to encourage vaccinations. They always do. But why would a larger death toll signify the need for more flu shots? Were they suggesting more deaths occurred because not enough people took their flu shot? Over the past few years more and more people had received flu shots,²⁴ yet it was this exact period in the late 1990s that the CDC declared the average deaths surged from 20,000 to around 36,000.

²² Census (2000, p4).

²³ Tanner (2003).

²⁴ CDC (2004), “Background on Influenza.”

The Marketing of Fear

While researching this article back in 2004, I came across the following message on the American Lung Association's website homepage: "Take Action! Don't Let the Flu Vaccine Shortage Happen Again!"²⁵ The link lead to a webpage urging viewers to support passage of the "Flu Vaccination Act of 2004" by offering to send a letter on the reader's behalf to their congressmen. Their explanation read: "The shortage of flu vaccine this year highlights the urgent need for a comprehensive response to influenza. ... Please ask your Senators and Member of Congress to support this important measure to ensure an adequate supply of flu vaccine."²⁶

The Act did not pass in 2004, but has been reintroduced in 2005.

As it is written, the Flu Protection Act of 2005 (S. 375, HR 813), will "ensure a sufficient influenza vaccine supply" by guaranteeing the profits of vaccine manufacturers like Chiron, Aventis-Pasteur, etc. It does this by requiring the CDC to pay the companies for any vaccines that "were not sold by the manufacturer through routine market mechanisms at the end of the influenza season for that year."²⁷ This is a remarkable guarantee that gives new meaning to the notion of corporate welfare.

In their annual report filed with the Securities and Exchange Commission, Chiron proudly reports: "Sales of our flu vaccines were \$332.4 million, \$90.0 million and \$74.7 million in 2003, 2002 and 2001, respectively."²⁸ Over the same time period, their U.S. flu vaccine production rose from 17.1 million to 38.6 million doses.²⁹ They declare, "Vaccines gross profit as a percentage of net product sales was 53% [in 2003]..." making it hard to understand why taxpayers need to protect profits like these.³⁰

The bill will also require the CDC to conduct a "public awareness campaign and education and outreach efforts" to emphasize, among other things, "The importance of receiving the influenza vaccine" and "Information that emphasizes the safety and benefit of recommended vaccines for the public good." (The 2005 Act removed the burden of emphasizing the vaccines' "efficacy," as was required in the 2004 version) How would this affect a doctor's clinical judgment about what is best for their patients? Is it the intention of Congress to change doctors' minds through legislative means?

The 2004 Act was submitted for consideration in Congress in January 2004, months before 50 million vaccines were pulled from the American market due to concerns of contamination. Had they known, one is only left to wonder whether they might have still required taxpayers to cough-up payment for all the "safe, effective, and beneficial" Chiron doses.

The truth is that the American regulatory agencies have already established close relationships to flu vaccine manufacturers.

On April 13 and 14, 2004, the American Medical Association (AMA) and CDC co-sponsored a "by invitation only" meeting. Called "The National Influenza Vaccine

²⁵ American Lung Association (2004), "ALA Homepage."

²⁶ American Lung Association (2004), "Take Action! Don't Let the Flu Vaccine Shortage Happen Again!"

²⁷ Flu Protection Act of 2005 (S. 375, HR 813).

²⁸ Chiron Annual Report (2004).

²⁹ Pinnell (2004).

³⁰ Chiron Annual Report (2004).

Summit,” it took place in Atlanta bringing together “organizational stakeholders in influenza vaccine research, production, distribution, and administration.”³¹ Besides AMA and CDC representatives, America's three flu vaccine manufacturers, Aventis-Pasteur, Chiron, and MedImmune, were invited, and also gave presentations. Their presentation files are available on the AMA website.³²

The most shocking presentation came from Dr. Glen Nowak, Ph.D., Associate Director for Communications at the National Immunization Program, a unit of the CDC. His talk, entitled “Planning for the 2004-05 Influenza Vaccination Season: A Communication Situation Analysis” makes evident the fact that the CDC is actively marketing flu vaccines in a fashion any vaccine manufacturer could only dream of.

Nowak's presentation discusses how to use the media to increase demand for the flu shot. The most disturbing element of his presentation is that the methodology employed is one of fear, not one of education. About halfway through his presentation, Nowak details his “Seven-Step 'Recipe' for Generating Interest in, and Demand for, Flu (or any other) Vaccination.” Nowak's recipe includes getting the media to carry stories of initial flu cases occurring “among people for whom influenza is not generally perceived to cause serious complications (e.g., children, healthy adults, healthy seniors).” “Medical experts and public health authorities publicly (e.g., via media) state concern and alarm (and predict dire outcomes) and urge influenza vaccination.” Done properly, he predicts, this will result in a “Framing of the flu season in terms that motivate behavior (e.g., as 'very severe', 'more severe than last or past years', 'deadly').”

Step 5 of the “recipe” calls for “Continued reports (e.g., from health officials and media) that influenza is causing severe illness and/or affecting lots of people helping foster the perception that many people are susceptible to a bad case of influenza.”

Nowak's slide on creating “motivating levels of concern and anxiety about influenza” brings previous years' flu seasons to mind. I can remember well my graduate student friends at Harvard University urging me to get my flu shot, in a frantic tone, as “supplies were running out!” I was told to rush in early. On this campus, we certainly had the “anxiety about influenza” Nowak is talking about.

Not having personally attended the conference, I cannot say how other attendees responded to Nowak's presentation. What I can say is that his presentation no longer surprises me. In fact, it helps me understand why officials say what they do.

On December 23, 2003, Dr. Julie Gerberding, Director of the CDC, and Dr. Nowak appear together on the National Public Radio program *All Things Considered*. Dr. Gerberding explains, “This is the time for Americans to really step up to the plate and get vaccinated against influenza, especially because this could be a worse-than-usual flu season.”³³ In the month prior to the show, demand for the flu vaccine had been low. Dr. Nowak recalls the situation: “At that point, the manufacturers were telling us that they weren't receiving a lot of orders for vaccine for use in November or even December. It really did look like we needed to do something to encourage people to get a flu shot.”

³¹ For a more complete description of the program, including participant listing and access to individual presentations, please see American Medical Association (2004), “2004 Influenza Vaccine Summit.”

³² American Medical Association (2004), “2004 Influenza Vaccine Summit.”

³³ NPR (2003), “Analysis: Balancing science and common sense in public health.”

While reading the NPR transcript, I suddenly imagined myself in a world where the regulatory agencies had become nothing more than the public relations agents for vaccine manufacturers...

The Flu Vaccine Crisis of 2004?

When I assess where my research has led me, it's hard not to lose all faith in the public health system—at least with regard to the flu.

When Chiron's license to manufacture the flu shot was suspended, I had my doubts about the media's portrayal of America as having entered a health crisis. What I learned is that fear is being marketed by trusted government agencies to plump up the profits of the vaccine makers; that the decision to bundle the flu with pneumonia is the only reason that influenza appears in the *Leading Causes of Death* list; that the statistical cartwheels that take annual death rates in the hundreds and blow them up into the tens of thousands wreak havoc with numbers, creating the illusion of a major problem while the underlying data support no such conclusion.

According to the CDC's own data over the past two decades, less than 1500 people per year died from the flu. How accurate is even this number? Probably not very accurate. Flu deaths are very difficult to measure. As we have seen, very few people actually die from the flu. Rather, the effect of the flu combined with many other things (e.g. acid-reflux medications, antibiotics, or simply old age), can make a poorly functioning immune system even weaker. From there, the chances one gets sick are higher. Sick with anything.

Part of the reason officials estimate flu deaths using models is because nobody really knows how many people die of the flu. As the CDC writes, “Influenza-associated deaths are not reportable conditions in the United States, and the average annual number of such deaths is unknown.”³⁴ The other reason is that the numbers we do have—an average of 1197 deaths per year over the 1990s—would be insufficient in motivating taxpayers to shell out hundreds of millions of dollars for vaccinations.

There are a few specialized laboratories where the flu does undergo surveillance: at select World Health Organization and National Respiratory and Enteric Virus Surveillance System facilities.³⁵ These labs receive and analyze samples of what they suspect to be the flu. Testing begins on calendar week 40 and ends on week 20 of the following year. At the height of “flu season” over the past five years, the peak percentage of specimens testing positive for the flu ranged between 23% and 35.2%.³⁶ All together, their data averages to around 12%. The most recent 2004-05 season averaged to 15%.³⁷ This means that when we think we've come down with the flu, the odds are not good that we really have the flu. Most likely, it's something else that's making us sick.

Sadly, these statistics and data are not used to reassure us we needn't be worried

³⁴ CDC (2004), “Update: Influenza-Associated Deaths Reported Among Children Aged <18 Years --- United States, 2003--04 Influenza Season.”

³⁵ CDC (2004), “2003 - 04 U.S. Influenza Season Summary.”

³⁶ CDC (2004), “2003 - 04 U.S. Influenza Season Summary.”

³⁷ CDC (2005), “Weekly Report: Influenza Summary Update. Week ending May 21, 2005-Week 20.”

sick over the flu. Instead, real statistics never get mentioned, and CDC models that defy common sense are doubly distorted by definition changes, a problem further confounded when the uncritical mass media amplifies everything CDC officials say – culminating in inducing the “concern and anxiety” that Dr. Nowak discussed in his presentation.

This is not to say that the flu is something we should never concern ourselves with. Rather, this report attempts to put the flu in some rational perspective and raise red flags about the way we have allowed officials to convince us of a distorted sense of reality through the language of fear.

It is hard to understand who would support measures like the Flu Protection Act of 2005 unless its backers are the vaccine manufacturers themselves. The CDC is already protecting the vaccine manufacturers’ interests by conducting multi-pronged campaigns to increase demand and thus secure profits.

With the 2004-05 flu season now behind us and the 2005-06 season still months away, there is time for Americans to calmly assess whether the flu is really something worth panicking over. The past year's flu season has turned out to be mild, despite the so-called “severe vaccine shortage.”

There are signs people within the establishment are disturbed by the ruling orthodoxy. In February, researchers at the NIH published a study which challenged CDC dogma. Looking at more than 30 years of data, they stated: “We could not correlate increasing vaccination coverage after 1980 with declining mortality rates in any age group.” One *AP* headline read: “Study finds flu shot doesn’t help elderly: NIH research shows vaccine has not saved any lives.”³⁸ And a *Reuters* article began: “Flu Shots May Not Save Lives – U.S. Study.”³⁹ The NIH findings were not reported in the *The New York Times* and *The Washington Post* wrote that “the study ... is bound to confuse the public.”⁴⁰

People will have to make up their own minds about whether to get a flu shot or not. It's not my business. As for me, everything I have learned has made me more confident I'm still better off without one. Shortage or no shortage, I'm not worried.

³⁸ Johnson (2005).

³⁹ Reuters (2005).

⁴⁰ Washington Post (2005).

Bibliography

American Lung Association (2004)

ALA Homepage, Available online: <<http://www.lungusa.org/>>. Retrieved 24 October 2004.

“Take Action! Don't Let the Flu Vaccine Shortage Happen Again!” Available online: <http://lungaction.org/campaign/flu vaccines_message/> Retrieved 27 October 2004.

American Medical Association (2004)

“2004 Influenza Vaccine Summit”, <<http://www.ama-assn.org/ama/pub/category/15156.html>> [Online].

Appleby, Julie and Schmit, Julie (2004)

“Is someone to blame in flu vaccine debacle?” *USA Today*, 12 November 2004. Available online: <http://www.usatoday.com/money/industries/health/drugs/2004-11-12-flu-cover_x.htm>. Retrieved 5 January 2005.

Arias E, Anderson RN, Hsiang-Ching K, Murphy SL, Kochanek KD (2003) “Deaths: Final data for 2001.” National vital statistics reports; vol 52 no 3., Hyattsville, Maryland: National Center for Health Statistics.

Bush, George W. (2004) “The Third Bush-Kerry Presidential Debate” Commission on Presidential Debates (October 13, 2004). Available online: <<http://www.debates.org/pages/trans2004d.html>>. Retrieved 28 October 2004.

Carrns, Ann (2003) “Flu Deaths Surge Amid Concerns For Elderly Care --- Report Says 36,000 People Die Per Year, With 90% Of Them 65 and Over”, *The Wall Street Journal* (8 January 2003, D2).

CDC (2002)

“Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP)” *MMWR* (April 12, 2002); 51 (RR03);1-31. Available online: <<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5103a1.htm>>. Retrieved 18 November 2004.

CDC (2003)

“CDC Assessing Influenza Vaccine Now In Supply Pipeline,” (5 December 2003) Available online: <<http://www.cdc.gov/od/oc/media/pressrel/r031205.htm>>. Retrieved 3 November 2004.

“Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices [ACIP].” *MMWR* 2003;53(RR06);1-40. Available online: <<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>>. Retrieved 28 October 2004.

CDC (2004)

“2003 - 04 U.S. Influenza Season Summary,” Available [Online]: <<http://www.cdc.gov/flu/weekly/weeklyarchives2003-2004/03-04summary.htm>>.

“Background on Influenza,” Available online:

- <<http://www.cdc.gov/flu/professionals/background.htm>>. Retrieved 29 October 2004.
- “Deaths—Leading Causes,” Available online:
<<http://www.cdc.gov/nchs/fastats/lcod.htm>>. Retrieved 29 October 2004.
- “Influenza (Flu) Pandemics,” Available online: <<http://www.cdc.gov/flu/avian/gen-info/pandemics.htm>>. Retrieved 5 November 2004.
- “Key Facts about the Flu and Flu Vaccine,” Available online:
<<http://www.cdc.gov/flu/keyfacts.htm>>. Retrieved 29 October 2004.
- “Update: Influenza-Associated Deaths Reported Among Children Aged <18 Years --- United States, 2003--04 Influenza Season,” (January 2, 2004) MMWR 2004;52(51);1254-1255. Available online:
<<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5251a4.htm>>. Retrieved 4 November 2004.
- CDC (2005)
- “Weekly Report: Influenza Summary Update. Week ending May 21, 2005-Week 20”. Available online: <<http://www.cdc.gov/flu/weekly/>>. Retrieved 12 June 2005.
- CDC Wonder (2005) United States Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), Compressed Mortality File (CMF) compiled from CMF 1968-1988, Series 20, No. 2A 2000, CMF 1989-1998, Series 20, No. 2E 2003 and CMF 1999-2002, Series 20, No. 2H 2004 on CDC WONDER On-line Database. <<http://wonder.cdc.gov/>>
- Census (2001) “Age: 2000” <http://www.census.gov/prod/2001pubs/c2kbr01-12.pdf>>. Retrieved 28 October 2004.
- Chiron Annual Report (2004) Form 10-K filed with the U.S. Securities and Exchange Commission. *Commission File Number: 0-12798*. Available online:
<<http://www.sec.gov/Archives/edgar/data/706539/000104746904006411/a2129339z10-k.htm>>.
- Chiron Press Release (2004) “Chiron Delays Fluvirin(R) Influenza Virus Vaccine Shipments: Vaccine Doses Expected to Be Available in October Pending Additional Tests.” (26 August 2004) Available online: <<http://phx.corporate-ir.net/phoenix.zhtml?c=105850&p=irol-newsArticle&ID=607482&highlight=>>>. Retrieved 28 October 2004.
- Flu Protection Act of 2004 (S. 2038, HR 3758).
- Flu Protection Act of 2005 (S. 375, HR 813)
- Gay, NJ, Andrews, NJ, Trotter, CL, et al. (2003) “Estimating Deaths Due to Influenza and Respiratory Syncytial Virus.” (21 May 2003) [Letter] JAMA. 289(19):2499-2502.
- Gerberding, J (2004)
- “Influenza Vaccine Supply Update” (27 August 2004). Transcript of press conference available at
<<http://www.cdc.gov/od/oc/media/transcripts/t040827.htm>>. Retrieved 28 October 2004.
- Glezen WP, Couch RB (2003) “Estimating Deaths Due to Influenza and Respiratory

- Syncytial Virus.” (21 May 2003) [Letter] JAMA. 289(19):2500.
- Laheij RJF, Sturkenboom MCJM, Hassing R-J, et al. Risk of community-acquired pneumonia and use of gastric acid-suppressive drugs. JAMA 2004;292:1955-1960. October 26, 2004.
- Manufacturer's Health products Regulatory Agency (MHRA, 2004) “Fluvirin influenza vaccine manufacturer's licence suspended” (6 October 2004). Available [online] <<http://www.mhra.gov.uk/news/2004/chironfluvaccine.htm>>. Retrieved 29 October 2004.
- Nowak, Glen (2004) “Planning for the 2004-05 Influenza Vaccination Season: A Communication Situation Analysis.” Available online: <http://www.ama-assn.org/ama1/pub/upload/mm/36/2004_flu_nowak.pdf>. Retrieved 5 November 2004.
- NPR (2003)
- “Analysis: Balancing science and common sense in public health” *NPR: All Things Considered*, 23 December 2003. Transcript obtained 23 October 2004 through Factiva.com (Dow Jones & Reuters).
- “Profile: Deaths from flu on the rise”, *NPR: Morning Edition* (8 January 2003). Transcript obtained 23 October 2004 through Factiva.com (Dow Jones & Reuters).
- Pinnell, Doug (2004) “Chiron Vaccines Presentation: National Vaccine Summit Meeting.” Available online: <http://www.ama-assn.org/ama1/pub/upload/mm/36/2004_flu_pinnell1.pdf>. Retrieved 5 November 2004.
- Reuters (2005). “Flu Shots May Not Save Lives – U.S. Study” (14 February 2005) Available online: <<http://olympics.reuters.com/newsArticle.jhtml?type=healthNews&storyID=7625047>>. Retrieved 15 February 2005.
- Simonsen L, Blackwelder WC, Reichert TA, et al. (2003) “Estimating Deaths Due to Influenza and Respiratory Syncytial Virus.” [Letter] (21 May 2003) JAMA. 289 (19):2499-2502.
- Simonsen L, Reichert TA, Viboud C, et al. (2005) “Impact of Influenza Vaccination on Seasonal Mortality in the US Elderly Population.” *Arch Intern Med* 165: 265-272 (14 Feb 2004).
- Johnson, Carla (2005) “Study finds flu shot doesn’t help elderly: NIH research shows vaccine has not saved any lives” *The State* (15 February 2005) Available online: <<http://www.thestate.com/mld/thestate/news/nation/10901563.htm>>. Retrieved 13 June 2005.
- Tanner, Lindsey (2003) “Flu deaths up sharply in U.S. since 1970s, largely because of aging population” (8 January 2003) Associated Press Newswires.
- Thompson WW, Shay D, Weintraub E, et al. “Mortality associated with influenza and respiratory syncytial virus in the United States.” (8 January 2003) JAMA. 289 (2):179-186.
- Washington Post (2005) “Flu Shots May Be Ineffective in Elderly” (15 February 2005) A9.