

InClass

A spotlight on faculty and their work

Voice of Reason

Before the camera and behind the scenes, Dr. William Schaffner strives to improve public health. By LISA A. DUBOIS

IT WAS OCT. 5, AND MEMBERS OF the National Vaccine Advisory Committee, who were gathered at a meeting in Washington, D.C., had hardly finished their first cup of morning coffee when someone walked into the room with the news. British regulators had shut down Chiron Corp. because of poor manufacturing practices, and the 46 to 48 million doses of this year's influenza vaccine the United States was expecting to receive would not be coming. That meant the U.S. was short about half its needed annual supply.

Soon afterwards the phone rang in the office of Clinton Colmenares, senior information officer and national news director for Vanderbilt University Medical Center. It was Dr. William Schaffner, speaking in hurried, hushed tones, "Clinton, you've got a story here. This is big time. Huge." Schaffner told him what was happening with the flu vaccine.

"OK," Colmenares responded. "When are you going to be available for interviews?"

By that evening Schaffner, chairman of Vanderbilt's Department of Preventive Medicine, had already conducted a number of television, radio, print and online interviews, assessing the problem and explaining strategies for addressing the vaccine shortage. Aware of the potential for a national panic attack, he tried to be balanced and optimistic, but he also chose to shoot straight about the seriousness of the situation. Later that night in a CBS interview, Schaffner was the first pub-

lic health professional to admit there may be deaths because of the flu-vaccine shortage.

"Bill is not a government employee, but as a senior spokesman for the communicable-disease sector, he can be as frank and as honest as he wants to be," says longtime friend and colleague Dr. Allen Kaiser, chief of staff at Vanderbilt Hospital. "He's a world authority on vaccines. And the social, ethical, moral

Vanderbilt. National reporters respect him and know he'll deliver a message that's on target and timely."

As a result, Schaffner is constantly called upon for insight and advice about an astonishing range of public health concerns. He has either authored papers on or been quoted in scientific journals and in the public media on such topics as influenza; smallpox vaccine; Hepatitis A, B and E; emerging diseases; water-quality investigations; tuberculosis outbreaks; SARS; HIV/AIDS; meningitis; streptococcus; tick-borne diseases; rabies; bioterrorism; food-borne illnesses; and the perceived relationship of childhood immunizations to SIDS and autism.

"The usual mode is for investigators to pick a narrow area and to become evermore expert," says Schaffner. "I've done the exact opposite. I've taken a discipline—epidemiology [the study of the causes and transmission of diseases within a population]—and I've applied it broadly and almost exclusively to issues of communicable diseases and how they occur in the community or among patients in our hospital. Also, the prevention of those communicable diseases, particularly through the use of vaccines, has evolved into another preoccupation of mine."

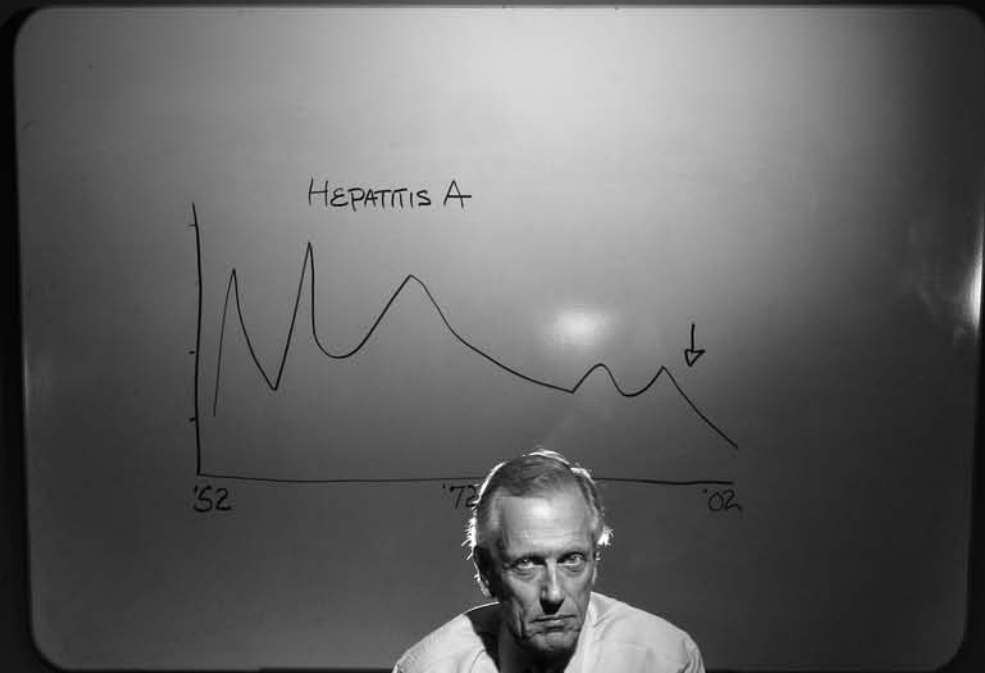


MARTY ORVILLE MYERS

and economical issues surrounding vaccines are enormous."

Since 1962, when Schaffner first arrived at Vanderbilt as an intern, he has worked on honing his skills, not only as an expert in communicable diseases and international public health policy, but also in articulating complicated health matters in a way that is understandable to the lay public. "He knows that by talking to one reporter, he can deliver a public health message and patient education to the entire country," Colmenares says. "In the eyes of the media, Bill legitimizes

Right: A world authority on vaccines, Dr. William Schaffner articulates complicated health matters in a way that is understandable to the lay public.



“In public health we’re always making decisions based on inadequate information. But there’s one difference: When we make those decisions, we’re on camera. As soon as you make a decision in public health, somebody sticks a microphone in front of you and asks, *‘Why did you make that decision?’* I’ve always considered that a challenge and great fun.”

The seeds for this preoccupation were planted during Schaffner's only departure from Vanderbilt—a two-year period, from 1966 to 1968, during which time he fulfilled his selective-service obligation as a commissioned officer in the U.S. Public Health Service and was assigned to the state health department in Rhode Island. There he developed a determination to “bring the public health sector in this country closer to the academic structure.” In other words, he was going to come back to Vanderbilt and establish close ties between the Medical Center and the Tennessee Department of Health (TDH).

At the time this concept of bridging the gap between public health and academia was more radical than it may now seem. Public health, after all, has little to do with the diagnosis and treatment of patients, so crucial to medical education. Instead it focuses on preventing illness in whole populations.

“I thought assisting, collaborating and cooperating with state health providers would bring added value to our school of medicine,” Schaffner says. “Rather than having bits of excellence, rather than being insular, I wanted Vanderbilt to reach out and be part of the warp and woof of the community. So I developed a relationship with the people at TDH. And I like to say I have a foot in each camp.”

In fact, Schaffner has become a pillar of the local, regional and statewide public health infrastructure. Starting in 1971 he began mentoring public health physicians who had been assigned by the Centers for Disease Control and Prevention (CDC) to carry out their two-year tours of duty in Tennessee, just as Schaffner had been assigned to Rhode Island.

In 1995, Schaffner scored a major breakthrough on this front. After training at the TDH, Dr. Allen Craig decided to stay on and is now Tennessee's state epidemiologist and director of its Communicable and Environmental Disease Services section. Craig was the department's first epidemiologist. Today there are five, and Schaffner has been involved in training four of them.

“The collaboration between the state health department and Vanderbilt University is outstanding and is probably unique in the country,” Craig says, adding that through the strength of Schaffner's support, the TDH was award-

ed a grant to begin an emerging diseases program. “The Medical School's infectious disease division has offered us tremendous lab support. We're partnering with the University to address major public health issues like emerging diseases.”

In addition to Craig, other Schaffner protégés who chose to stay in Nashville are Dr. Timothy Jones; Dr. Connie Hadley, now directing the state tuberculosis control program; and Dr. Kelly Moore, who runs the state immunization program. Although Dr. David Kirschke left Nashville, he is now working in the North-eastern Tennessee regional public health office.

“We bring great talent into the state, and we keep it!” crows Schaffner. “Our state health department's communicable disease control division is now, in terms of talent, second to none in the country.”

Medical practitioners, he says, have always been referred to by two terms. One is “physician,” from the Greek *physic*, meaning “medicine” and referring to those who diagnose and treat. But more commonly, they are known as “doctor,” from the Latin term for “teacher.” “The teaching is as much a part of the practice of medicine as the *physic*,” Schaffner says.

Back at Vanderbilt, in his role as chairman of preventive medicine, Schaffner has overseen the development of two training programs: the master's program in public health, created by faculty members Wayne Ray and Dr. Marie Griffin, and a biostatistics training program, which has grown so large that it has spun off into its own department chaired by Dr. Frank E. Harrell Jr. Since 1970, Schaffner also has headed VUMC's Infection Control Committee.

“Bill's forte has been in reading all the information from around the globe and being a leader in containment strategies for communicable diseases,” says Dr. Allen Kaiser. “Probably more than anybody else, he knows what happens when germs are spread within a community. He represents Vanderbilt, and as a fellow member of Vanderbilt, I am more respected around the country because of what he's done.”

Schaffner, in fact, is profoundly aware of his responsibility as one of the Medical Center's more visible ambassadors. “Believe me, every time I open my mouth I am mindful

of that,” he says.

When the National Vaccine Advisory Committee advisers heard about the flu-vaccine shortage, they first experienced a wave of shock, then depression. However, they soon took a collective breath and switched into coping mode. “That's what we do in public health,” Schaffner says. “We're always given lemons, but boy, do we know how to make lemonade.”

Immediately, representatives of the CDC convened an emergency teleconference with members of the National Vaccine Advisory Committee and others to plan the steps necessary for addressing the problem. They were able to clarify how many flu shots were contaminated and therefore missing; how many would be coming from the other manufacturer, Aventis; and how many doses of the non-injectable FluMist vaccine its manufacturer, MedImmune, could provide. They then began to adjust the national recommendations for who should have access to the limited supply. And, in order to reduce public confusion, they had to make certain that everyone who would be quoted in the press or on television would be trilling the same tune.

By noon Schaffner and others were ready for their cue to go on. Looking distinguished and reassuring with his silver hair and white lab coat, he began speaking to the major news outlets. “Supplies are a little tight right now,” Schaffner said to CNN's Wolf Blitzer. “We have to realize that the era of dirt-cheap vaccines is over,” he told the *New York Times*. “If you want some redundancy in the system to help you deal with glitches that will occur from time to time, you need more [vaccine] manufacturers,” he said to the *Los Angeles Times*. And on he went over the next several weeks, providing informed analysis to a wide spectrum of news sources.

Schaffner compares this aspect of his job to a physician caring for patients in an intensive care unit, having to make quick decisions based on inadequate information. He says, “In public health we're always making decisions based on inadequate information. But there's one difference: When we make those decisions, we're on camera. As soon as you make a decision in public health, somebody sticks a micro-

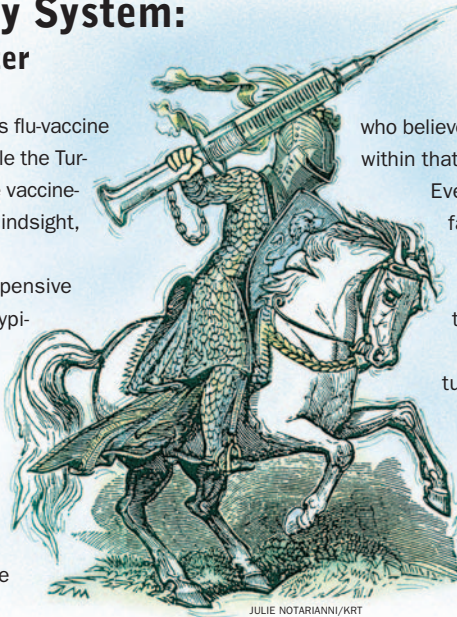
The Flu Vaccine Delivery System: Tottering on the Edge of Disaster

The October surprise concerning this year's flu-vaccine shortage was like the final burp from Yertle the Turtle, creating a domino effect that sent the vaccine-delivery kingdom tumbling into the mud. Yet, in hindsight, what happened was hardly a surprise at all.

First, vaccines have become increasingly expensive to manufacture and deliver. Influenza viruses typically originate each year in the Far East, often in chickens and other fowl before being transferred to humans. Because flu strains mutate quickly, one strain that appears one year will not necessarily emerge the following flu season. As a result, influenza experts gather annually in Geneva to determine which strains are on the horizon and will cause the most disease worldwide.

Manufacturers then spend the next six months growing up those strains in chicken eggs—typically one egg per dose of vaccine. That translates to thousands of chickens that produce the 100 million doses of vaccine required by the United States each year. Once a vaccine is mixed into pharmaceutical form, it still must be delivered—and at a price affordable to the average citizen.

In the 1980s and early '90s, vaccine manufacturers began to exit the business. The FDA was ramping up costly safeguards to protect against contamination, pharmaceutical companies were merging into massive conglomerates that considered vaccine production a low priority, and suppliers grew increasingly fearful of liability litigation if patients suffered side effects. To stem the exodus, the United States implemented the National Vaccine Compensation program, placing a small surcharge on each dose of vaccine sold. Now, rather than sue the vaccine maker, those



who believe they've had a bad reaction must file a complaint within that program.

Even with that protection in place, vaccine manufacturers have continued to drop out, lured away by the prospects of giant profits from so-called blockbuster drugs—medicines that people must take on a regular basis for a long period of time.

Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, recently explained to the Associated Press that a year's supply of Lipitor costs \$1,608, and the equivalent supply of Viagra, \$3,500. Compare that to the \$7 to \$10 drug companies earn from flu vaccine. Plus, because the flu vaccine is reconstituted each year, any doses not used in a given season must be discarded. Past suppliers

have been forced to destroy millions of unused dosages—literally watching their profits go up in smoke.

In light of this history, the U.S. was down to two manufacturers, Chiron and Aventis Pasteur, for the flu shot deemed safe for the general public, and one manufacturer, MedImmune, for the inhaled FluMist vaccine, recommended for healthy people ages 5 to 49. It's no wonder, then, that when Chiron was shut down because it failed to meet quality-assurance standards, America's public health officials, lacking a backup supplier, suddenly began scrambling.

Ironically, many of these same public-health officials have long warned that the nation's current vaccine-delivery system is a house of cards. "Perhaps," Vanderbilt's Dr. William Schaffner told the *New York Times*, "this event will be like the drunk who has to bottom out before [he] seeks therapy."
—LISA A. DUBOIS

phone in front of you and asks, 'Why did you make that decision?' I've always considered that a challenge and great fun."

This attitude that embraces both good and bad press coverage has made Schaffner somewhat of an anomaly in academic medicine—a part of Vanderbilt, but also apart from it. In a field of work that requires attention to the minutest of details, he has made a career out of stepping back and assessing the big picture.

In the *New York Times*, he recently noted that the Bush administration promised to dedicate \$5.6 billion for developing vaccines against anthrax and other biological agents—for diseases that don't exist anywhere in the world. "What we need,"

Schaffner insisted, "is an adult immunization program for diseases that kill tens of thousands every year."

Perhaps government officials should pay attention to his argument. For 42 years he has been crusading on behalf of public health initiatives, and again stepping back to get the global view, he sees the payoffs starting to roll in.

"We just built a new Vanderbilt Children's Hospital," he says. "What ward didn't we put in it? We didn't put in a polio ward. Why? Vaccine! We're now on the lip of eliminating polio from the world. Tell me that prevention is not the highest goal of medicine!"

While other physicians gain immediate gratification from interacting with patients

and families, public health doctors have to get their kicks out of implementing programs and looking at curves on graphs that show a reduction in disease, he says. "It's an interesting and curious way to get satisfaction," Schaffner admits. "But I feel it's the greatest kind of achievement when you don't have to build a children's hospital with a polio ward."

Lisa A. DuBois has been a freelance writer since 1985, penning stories for newspapers, magazines, radio and video. She has worked as a regular contributor to several Nashville publications, including the Tennessean newspaper. Her husband, Ray, is on the faculty at Vanderbilt University Medical Center.