

TESTIMONY

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON GOVERNMENTAL AFFAIRS

***"PROTECTING OUR KIDS: WHAT IS CAUSING
THE CURRENT CHILDHOOD VACCINE SHORTAGE?"***

**PRESENTED BY:
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Good morning, Madam Chairwoman, members of the Committee, I am Dr. Tim Doran, a practicing pediatrician who has taken care of children for almost 20 years. I am also Chairman of Pediatrics at the Greater Baltimore Medical Center, a community hospital in Baltimore, Maryland. On behalf of the American Academy of Pediatrics, I would like to thank you for the opportunity to testify today about the current shortage in childhood vaccines.

The American Academy of Pediatrics (AAP) is an organization of 55,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. My testimony today reflects not only my experiences from my pediatric practice but also those of colleagues from across the United States. As a practicing pediatrician, I would like to share with you my perspective on the current vaccine shortage, discuss the consequences this has had on vaccine delivery to my patients and their parents, and the impact on my practice.

Overview:

As primary care pediatricians, prevention of disease through immunization is a priority. It is an integral component and major goal of the comprehensive pediatric health care we provide to infants, children, adolescents and young adults. Overall, we deliver approximately 75% of all immunizations. The predictable delivery of safe and effective vaccines is central to our goal of disease prevention.

Immunization is one of the greatest public health achievements of the 20th century and has saved millions of lives. Since the widespread use of vaccines, millions of children have avoided terrible diseases that can cause great suffering and in some cases, death. For example before immunization, polio paralyzed 10,000 - 25,000 children and adults, rubella (German measles) caused birth defects and mental retardation in as many as 20,000 newborns, and measles infected millions of children, killing 400 - 500 and leaving thousands with serious brain damage. Immunizations have reduced by more than 95 to 99 percent the vaccine-preventable infectious diseases in this country.

In the last decade a number of positive changes have occurred in the delivery of vaccines to infants, children and adolescents. Now, in addition to diphtheria and tetanus toxoids and acellular pertussis (DTaP), polio, measles, mumps, rubella (MMR), and Haemophilus influenza type b (Hib), several new vaccines have been added to the routine vaccination schedule for children, including the hepatitis B vaccine (added in 1994), varicella (chicken pox – introduced in 1995), and the pneumococcal conjugate vaccine (added in 2000).

However, recently, there have been some less-positive changes. In my 22 years of practicing pediatrics, including my pediatric residency training, I have never witnessed a vaccine shortage such as we see today. My colleagues and the parents of my patients are alarmed about the current situation. The recent disruptions and shortages – remarkable for both the number of different vaccines involved as well as the scarcity of the

available supply – have been a wake-up call to the average practicing pediatrician as we come to the realization that the vaccine supply, and perhaps the overall vaccine system, is far more fragile than we had imagined.

Pediatric Practices:

My office experience has been that the distribution of the required childhood vaccines is spotty and unpredictable. In recent months, my practice has seen shortages in several vaccines. These shortages reflect the national disruption of routinely administered vaccines against the eight out of 11 vaccine-preventable childhood infectious diseases. The problem is particularly acute with the new 7-valent pneumococcal conjugate vaccine (PCV7, Prevnar). This vaccine helps protect children from life-threatening meningitis (an infection of the covering of the brain) and blood infections. Many of my pediatric colleagues, such as those in Wisconsin, are completely out of this vaccine. According to a pediatrician from New Mexico, his high-risk patient population of American Indian/Alaskan Native infants currently has no supply of PCV7. This is especially troublesome because he recently diagnosed a four-month old Navajo infant with a case of pneumococcal meningitis - a vaccine-preventable childhood infectious disease. Also in short supply nationally is the tetanus-diphtheria toxoids (Td) vaccine. Td has been in limited supply for over a year now. This has affected the ability to give teens the booster Td they need. Other vaccines in short supply include DTaP, varicella, and MMR.

A pediatrician in St. Charles, Missouri recently called the offices of the American Academy of Pediatrics to describe his serious vaccine shortage problem. He has a small private practice - two pediatricians and one nurse practitioner. He has had difficulty since last September in obtaining both the Prevnar and varicella vaccines. Currently he does not have a supply of either vaccine. Imagine his dismay when he was advised by a patient's mother, who arrived with her son for his one year well-child visit, that she believed her son had been exposed to chicken pox. If he had any varicella vaccine to offer the patient, research data has found that the child's disease could be ameliorated by vaccination.

As you have heard from the CDC representative, several factors are contributing to the fragile supply in this country. Many vaccine manufacturers are facing increased profitability challenges that force them to re-think their place in the market. For example, the U.S. Food and Drug Administration's Good Manufacturing Practices are being enforced more stringently, which, in some cases, will mean that vaccine makers must build new plants to be in compliance. Some manufacturers have decided it's not worth the investment and have dropped out of the market. For others, poor demand – and thus, poor sales – has been too difficult to surmount, as was the case with the recent withdrawal from the market of the Lyme vaccine by Smith-Kline-Beecham.

Also contributing to the shortages are production issues (including unexpected demand for a vaccine that exceeded supply), decreased yields of the biologic materials used in certain vaccines, the elimination of some vaccines containing thimerosal as a preservative, and insufficient vaccine stockpiles.

At times I have had to explore alternative ways to obtain the full supply of vaccines my practice needs. Sometimes I have been more successful obtaining vaccines directly from pharmaceutical representatives than through the bulk purchasing mechanism through the hospital pharmacy. At other times, I borrowed from other practices. There was no opportunity to plan in any reasonable way to anticipate the supply, and unfortunately the pharmaceutical representatives are of little help in predicting when depleted vaccines will become available.

Impact and Consequences:

The real-life impact of these shortages can not be denied. An estimated 11,000 babies are born each day in the United States, each requiring 20 doses of vaccine by age 18 months to be protected against 11 childhood diseases. In addition, there are booster vaccines, such as Td, given in adolescence. A vaccine shortage quickly impacts thousands of families every day.

The parents of my patients have been understandably anxious when they learn that a vaccine is unavailable. They know that there is a small but finite chance that their child might become ill with an otherwise easily-preventable disease because of a delayed or altogether missed vaccine. And many of these diseases, such as measles and meningitis, can be devastating – even fatal – in young children.

Because of recent media publicity and campaigns by anti-vaccine groups, I spend a significant amount of time with many parents reassuring them that our vaccines are safe and beneficial. I cannot help but wonder how my credibility, and that of my colleagues, suffers when I then have to explain that these important and safe vaccines are not available for their young child, now at risk for contracting a life-threatening illness. This unduly disrupts the confidence between doctor and parent - a trust that is fundamental to the parent - pediatrician relationship.

Additionally, children who are not vaccinated could possibly be denied entry to school or access to day care. How will school systems deal with increasing numbers of school-age children registering without having completed the vaccination requirements? What will struggling working parents do if their care provider bars their child from day care because he or she is behind on vaccinations? Moreover, what will parents do when children become unnecessarily sick with vaccine-preventable illnesses that prevent them from attending school or day care and parents miss days from work to care for their sick child?

Along with the stress on the vaccine delivery system and on parents and patients, the vaccine shortage has an administrative impact on my practice as well. We must now create a system of call - back lists and tickler

files to reach those most in need of missed vaccines when they become available. My experience and that of other pediatricians has been that these systems are not very reliable or effective. Even in a relatively affluent population, the level of compliance with these call-backs is only fair. The need to effectively track patients and get them back in the office to receive vaccines adds a heavy administrative burden on practices that are already overwhelmed with complex billing issues, referrals, insurance verifications, coding, school and camp forms, medication permissions from schools, prescription refills, phone calls from sick patients, inventory controls, OSHA compliance and documentation, and prolonged holds on the telephone for insurance approvals for certain drugs and procedures.

All this is occurring at a time when the Centers for Medicare and Medicaid Services (CMS) has failed to recognize the physician work associated with the provision of vaccines to patients. This will result in inadequate payment for these services, which will further exacerbate and threaten the already fragile vaccine delivery system. Such lower payments create a disincentive for a pediatrician and other doctors to administer childhood immunizations in a child's "medical home."

Conclusion:

As you can see, the fragility of this nation's vaccine supply is a broad, complex problem, and its solution can only come from the strong leadership and the close involvement of all stakeholders. I believe it is crucial to our children's health that we continue to work towards ending the current shortage as well as look for solutions to avoid future disruptions in supply. I am grateful to have been here today to share my perspective as a practicing pediatrician.

Thank you.