

Facing the Shortage

Pediatricians and pharmaceutical companies unite to end the vaccination shortage



Mary Anne Jackson, M.D., attends to one of her patients at Children's Mercy Hospital, Kansas City. In June, Dr. Jackson addressed a Senate committee on the recent shortages in children's vaccines.

by Ann Muder

Mary Anne Jackson, M.D., '78, gets requests to talk to many groups about childhood vaccinations. She estimates that she's given over 500 speeches in her career, talking to medical personnel from school nurses to pediatricians.

She never imagined that she'd one day speak to the U.S. Senate.

Dr. Jackson was contacted by Senator Jean Carnahan's office to speak at a Senate hearing in June about the unprecedented vaccine shortages in the United States. She, along with one other pediatrician, a pharmaceutical representative, and representatives from the FDA and CDC, spoke to the Senate committee on why the shortage happened and its impact on our country's children. As professor of pediatrics and chief of pediatric infectious diseases at Children's Mercy Hospital and Clinics in Kansas City, Dr. Jackson faces this issue on a daily basis.

"It worries me every time I see a child come in with a vaccine-preventable disease," she says. "The first question is, has this child been immunized? And if not, why not? Was it because the parents didn't take advantage of the vaccine? Or was it not available because of the shortage? This shortage has complicated what has already been a complicated problem in the first place."

An unprecedented crisis

The shortage affected vaccines that prevent eight out of 11 childhood diseases: tetanus, diphtheria, pertussis, pneumococcal infection, measles, mumps, rubella, and varicella (chickenpox).

Walter A. Orenstein, M.D., Director of the National Immunization Program for the CDC, reported at the hearing that the vaccines most significantly affected have been the Td (tetanus and diphtheria) and pneumococcal vaccines, each showing a 40 percent decrease in the number of doses distributed in the U.S. The varicella vaccine doses decreased between 26 and 29 percent and MMR doses, 15 percent.

In order to minimize the risk to children, the CDC recommended that physicians prioritize their vaccines and keep a list of patients to call back when vaccines were available. But according to Dr. Jackson, pediatricians generally are not able to prioritize the medicine because they can't predict when the next shipment will arrive.

"It wasn't like they were told they would be getting a new supply in a couple

of months," she says. "They would be due on Friday, and then they just wouldn't show up. So it really just wasn't practical in a pediatrician's office. It turned out that when they looked at this nationally, only 40 percent of pediatricians were minding the recommendations. It wasn't that 60 percent were ignoring it – it was just that it wasn't practical."

According to Jackson, even though pediatricians are keeping lists and calling back patients, there are no guarantees that the parents will come back in. "For some working parents, many just choose to wait until their next appointment to come in, so that already set their baby back a couple of months."

While the shortage is expected to be over by the end of this year, Dr. Jackson says that we probably won't know the full impact of the shortage for another year or two. "With current national immunization coverage rates, we're at 80 percent," she says. "I think the impact of this shortage, which has been going on for over a year, is that we may drop our rates by 10 percent. Below 80 percent, I think we're really at risk for starting to see an outbreak of diseases again. You're basically a plane ride away from many of these diseases."

Pharmaceutical issues

Several reasons for the shortage were cited at the hearing, mostly related to marketplace and economic factors. One of the main reasons was the fact that some drug companies are dropping out of the vaccine market. Because there are only four major vaccine manufacturers, any disruption in production causes a major impact on the supply of vaccinations.

According to Tom Zink, M.D., '80, vice president in charge of Immunization Practices and Scientific Affairs at GlaxoSmithKline (GSK), part of the reason some companies have dropped out is the decline in the price of vaccines.

"Vaccines have been devalued," he says. "When diseases aren't seen or experienced anymore, people become complacent and take the protection afforded by vaccines for granted. So when the perceived value drops, people don't think they should have to pay as much."

Another factor cited by the CDC at the hearing was manufacturers' production time. Because the process of developing a vaccine includes complex biological processes, producing a vaccine that has already been approved takes about six to

eight months. Supply can also be reduced as a result of manufacturing regulations and government recommendations, such as when officials recommended that companies remove mercury-containing preservatives from vaccines.

One of the solutions suggested at the hearing was to expand governmental stockpiles so there would be enough vaccines to draw from in the event of another shortage. "The CDC is still working on the logistics," says Dr. Zink. "Whether it would be a 'Fort Knox' approach bringing all the vaccines together, or whether the vaccines would be stored with the manufacturers, that is, held 'in escrow' and rotated out into the market every six months, has yet to be determined."

Another possible solution recommended at the hearing was to boost the Vaccine Injury Compensation Program, which protects companies from being sued for serious side effects from the vaccinations.

"We have vaccines that are carefully looked at and are very safe with perhaps very rare side effects," says Dr. Jackson. "But all you have to do is mention autism, and there are some individuals who are concerned there is a link to vaccines. Medical litigation could be one reason why the companies want to pull out of providing this type of vaccine."

"We need to do whatever it takes to show those companies who would give up that the business is still viable," says Dr. Zink. "We need to reestablish the importance of vaccines and take a hard look at the barriers to entry such as regulatory hurdles and threats to market stability in order to build a climate that allows companies to survive and continue to manufacture these vaccines."

Changing the rules

Physicians and industry representatives at the hearing agreed that without changes in policy for both government and the pharmaceutical industry, the causes for the shortage are likely to persist.

"One thing I was encouraged by at the hearing was it seemed obvious there were some good solutions to help prevent this from happening in the future," says Dr. Jackson. "The senators were very well versed and asked excellent questions. You worry that when something is political or in any bureaucracy that it will get tied up in red tape. But this seems like they will get through the red tape." ■