Approved: 3-21-00
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chairperson Sandy Praeger at 10:00 a.m. on March 16, 2000 in Room 526-S of the Capitol.
All members were present except:
Committee staff present: Norman Furse, Revisor of Statutes
Lisa Montgomery, Revisor of Statutes
Hank Avila, Legislative Research Department
JoAnn Bunten, Committee Secretary

Conferees appearing before the committee:
Bob Williams, Executive Director, Kansas Pharmacists Association
Sally Finney, representing Kansas Public Health Association, Inc.
Chris Collins, Director of Governmental Affairs, Kansas Medical Society
Tim Moore, M.D., Department of Health, KDHE
Others attending: See attached list

Hearing on HB 2759 - Pharmacists authorized to administer drugs under certain conditions

Bob Williams, Executive Director, Kansas Pharmacists Association, testified before the Committee in support of **HB 2759** which would allow pharmacists to administer adult vaccinations (eighteen years and over). Mr. Williams noted that the bill requires pharmacists to obtain a vaccination protocol with a physician and successfully complete a course of study and training approved by the American Council on Pharmaceutical Education or the State Board of Pharmacy. The pharmacist may not delegate to any person the authority granted under the act to administer a vaccine. He pointed out that according to the World Health Organization more than half of elderly Americans do not receive a flu vaccinations. (Attachment 1)

Sally Finney, representing the Kansas Public Health Association, Inc., expressed her support for **HB 2759** and noted that allowing pharmacists to administer immunizations would be a positive step towards reducing serious health complications and deaths from vaccine-preventable diseases in Kansas. She also urged the Committee to not amend the bill to limit its scope to just influenza and pneumonia. (Attachment 2)

Chris Collins, Director of Governmental Affairs, Kansas Medical Society, expressed her support for the intent of **HB 2759** but cautioned the Committee that the bill also raises the specter of future scope of practice concerns. Ms. Collins proposed an amendment that would limit the administering of vaccines to just influenza or pneumonia as shown in a balloon of the bill attached to her written testimony. (Attachment 3)

Tim Moore, M.D., Department of Health, KDHE, speaking for Dr. Gianfranco Pezzino, expressed support for the bill and noted that this proposed legislation would make vaccines more easily accessible especially in the rural areas. He also brought the Committee's attention to the importance of accurate record keeping that would show what vaccines each individual received in order to prevent the administration of unnecessary vaccinations to individuals already immunized. He also felt the standards adopted in protocols should be equivalent to those in place in private medical practices where immunization records are usually retained for at least ten years. Other issues Dr. Moore asked the Committee to consider related to whether pharmacists would forward a notice regarding the vaccination to the "medical home" of each individual they immunize and whether a pharmacist would be able to access medical records containing information on previous immunizations received by an individual. (Attachment 4) Written testimony expressing concerns with the bill was received from Keith Wright, MD, Kansas Academy of Family Physicians. (Attachment 5)

During Committee discussion Chip Whelan, Kansas Osteopathic Medicine, called the Committee's attention to the liability issue and the "Vaccine Injury Compensation Act" enacted by Congress. Other concerns that were discussed by the Committee related to physician protocol and insurance reimbursement. Two issues raised were the necessity of immunization records should be submitted to the primary care physician, and if no primary physician is available, the pharmacist should encourage the vaccinee to obtain one. The Chair noted that staff will draft a balloon of the bill showing the proposed amendments that were suggested for the Committee's consideration.

Adjournment

The meeting was adjourned at 11:00 a.m.
The next meeting is scheduled for March 17, 2000.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
GUEST LIST

DATE: 3-16-00

NAME	REPRESENTING
Patrick J. Hurley	Ks Academy of Family Physicians
LARRY FROELICH	Ks BOARD of PHARMACY
BOB WILLIAMS	Ks. Physicians Assoc.
Ken Bonne	Hein/Lwer Chrtd.
Tim Monroe MD	KS Dept. of Health & Envr.
KEITH R LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
MICHAEL MOSER	KDHE
Chris Collins	KMS
BOB ANDERSON	KS. PHARMACISTS ASSOC.
Danelle Chauncey	University of Kansas School of Pharmacy
Julie Chase	Univ. of Kansas Medical Center
Bill Sneed	MERCK
Michelle Peterson	PhRMA
Karen Braman	SRS
Nancy Zogleman	Pfizer
Tom Rickman	AVENTIS
Anne Spiess	Peterson Public Affairs Group
Chip Wheelen	Osteopathic Assoc.

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ROBERT R. (BOB) WILLIAMS, M.S., C.A.E.
EXECUTIVE DIRECTOR

TESTIMONY
HB 2759
Senate Public Health & Welfare
March 16, 2000

My name is Bob Williams. I am the Executive Director of the Kansas Pharmacists Association. Thank you for this opportunity to address the committee regarding HB 2759.

HB 2759 will allow pharmacists to administer adult vaccinations (eighteen years and over). The bill requires pharmacists to obtain a "vaccination protocol" with a physician and successfully complete a course of study and training approved by the American Council on Pharmaceutical Education (ACPE) or the State Board of Pharmacy that includes vaccination storage, protocols, injection technique, emergency procedures and record keeping. The bill also states that the pharmacist "may not delegate to any person the authority granted under this act to administer a vaccine."

As many of you know, influenza and pneumonia are the sixth leading cause of death in the United States. Influenza and its complications account for 10,000 to 40,000 excess deaths annually in the U.S., of which more than 80% occur in the elderly. According to the World Health Organization, more than half elderly Americans do not receive a flu vaccination. According to the Kansas Foundation for Medical Care, the influenza immunization rate for 1996 was 47.3% and 48.7% for 1997. I have been unable to obtain rates for 1998 and 1999. According to *Partnership for Prevention*, a national organization whose mission is to increase the priority for prevention, one of the six reasons listed for individuals not receiving

Senate Public Health and Welfare
Date: 3-16-00
Attachment No. 1

immunizations is "Lack of patient-friendly, easily accessible immunization services in the community." What could be more convenient, friendly, and accessible than your local community pharmacy?

Attached to my testimony is a list of thirty states that currently permit pharmacists to administer vaccinations. Please note that all of the states surrounding Kansas permit their pharmacists to administer vaccinations. In February 1999, South Carolina reported the largest rate increase for influenza immunizations in the country for adults ages sixty-five and older. The increase occurred from 1995 to 1997 which corresponds to when pharmacists began administering vaccinations. In an article published in the *South Carolina Pharmacy Journal,* Dr. Blake Williams, South Carolina Medical Review Director of Operations, is quoted as saying: "We are fortunate that South Carolina is a state that permits pharmacists to immunize against influenza."

Tennessee allowed pharmacists to administer immunizations in 1998. In the fall of 1999 the Tennessee Pharmacists Association asked community pharmacists to participate in a survey of their patients to validate the pharmacist's value in the immunization process. *Seventy-seven percent* of the patients said receiving an immunization at a pharmacy was easier than at any other place; *eighty-eight percent* of the respondents said pharmacies administer immunizations at more convenient times; *sixty-four percent* said they trust their pharmacists about the same as other immunization providers and *ninety-five percent* of the survey population said they would receive their immunizations at a pharmacy again next year.

The Wisconsin Pharmacists Association began an immunization program in 1999. Less than 100 pharmacists participated the first year. In a survey of participating pharmacists, they reported administering 4949 flu vaccines and 591 pneumococcal vaccines. No serious adverse reactions were reported.

Pharmacists providing immunizations have become so prevalent, the American Pharmacists Association now provides a "list-serve" for pharmacists who are actively involved with the administering of immunizations. A sample of the January 21, 2000, Immunization List-Serve is attached.

I have also attached a letter from Dr. Jose F. Cordero, Deputy Director, National Immunization Program, Centers for Disease Control and Prevention that states: ". . . the CDC comprehensively reviewed the educational materials for *Pharmacist-Based Immunization Delivery: A National Certificate Program for Pharmacists*. The review showed the program adequately addresses CDC's national vaccine standards and appropriately prepares pharmacists to assist public health officials with vaccine delivery. Overall, the CDC felt the program was of high quality and was pleased to recognize the effort."

Lastly I have attached a sample "Immunization Protocol," "Protocol for Management of Severe Allergic/Anaphylactic Reactions," "Vaccine Administration Record" and "Screening Questionnaire for Adult Immunization" for your review.

In summary, HB 2759 will permit pharmacists to administer adult vaccines only. It clearly states the requirements, restrictions and certification necessary in order for a pharmacist to administer vaccinations. Kansas pharmacists have been participating for a number of years with the Kansas Partners in Wellness Coalition (managed by the Kansas Foundation for Medical Care) to increase the immunization rate in Kansas. As stated previously, access is one of the barriers to obtaining vaccinations. HB 2759 will be a step in the right direction to eliminating that barrier.

Thank you.

From: mcr@mail.aphanet.org <mcr@mail.aphanet.org>
To: apha-ssb@eGroups.com <apha-ssb@eGroups.com>
Date: Friday, January 21, 2000 9:27 AM
Subject: [apha-ssb] Immunization List serve January 21, 2000

APhA Immunization Update
A list-serve provided by the American Pharmaceutical Association
Janury 21, 2000

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IN THIS ISSUE:

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I. Recommended Childhood Immunization Schedule -- United States, 2000

Each year, CDC's Advisory Committee on Immunization Practices (ACIP) reviews the recommended childhood immunization schedule to ensure it remains current with changes in manufacturers' vaccine formulations, revisions in recommendations for the use of licensed vaccines, and recommendations for newly licensed vaccines. This report presents the recommended childhood immunization schedule for 2000 and explains the changes that have occurred since January 1999.

Since the publication of the immunization schedule in January 1999 (1), ACIP, the American Academy of Family Physicians, and the American Academy of Pediatrics have recommended removal of rotavirus vaccine from the schedule, endorsed an all-inactivated poliovirus vaccine (IPV) schedule for polio vaccination, recommended exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series, and added hepatitis A vaccine (Hep A) to the schedule to reflect its recommended use in selected geographic areas (2). Detailed recommendations for using vaccines are available from the manufacturers' package inserts, ACIP statements on specific vaccines, and the 1997 Red Book (3). ACIP statements for each recommended childhood vaccine can be viewed, downloaded, and printed at CDC's National Immunization Program World-Wide Web site, http://www.cdc.gov/nip/publications/ acip-list.htm.

Removal of Rotavirus Vaccine from the Schedule

On October 22, 1999, ACIP recommended that Rotashield[Registered]* (rhesus rotavirus vaccine-tetravalent [RRV-TV]) (Wyeth Laboratories, Inc., Marietta, Pennsylvania), the only U.S. licensed rotavirus

vaccine, no longer be used in the United States (4). The decision was based on the results of an expedited review of scientific data presented to ACIP by CDC. Data from the review indicated a strong association between RRV-TV and intussusception among infants 1-2 weeks following vaccination. Vaccine use was suspended in July pending the ACIP data review. Parents should be reassured that children who received the rotavirus vaccine before July are not at increased risk for intussusception now. The manufacturer withdrew the vaccine from the market in October.

Inactivated Poliovirus Vaccine for All Four Doses

As the global eradication of poliomyelitis continues, the risk for importation of wild-type poliovirus into the United States decreases dramatically. To eliminate the risk for vaccine-associated paralytic poliomyelitis (VAPP), an all-IPV schedule is recommended for routine childhood vaccination in the United States (5). All children should receive four doses of IPV: at age 2 months, age 4 months, between ages 6 and 18 months, and between ages 4 and 6 years. Oral poliovirus vaccine (OPV), if available, may be used only for the following special circumstances:

1. Mass vaccination campaigns to control outbreaks of paralytic polio.
2. Unvaccinated children who will be traveling within 4 weeks to areas where polio is endemic or epidemic.
3. Children of parents who do not accept the recommended number of vaccine injections; these children may receive OPV only for the third or fourth dose or both. In this situation, health-care providers should administer OPV only after discussing the risk for VAPP with parents or caregivers.

OPV supplies are expected to be very limited in the United States after inventories are depleted. ACIP reaffirms its support for the global eradication initiative and use of OPV as the vaccine of choice to eradicate polio where it is endemic.

Acellular Pertussis Vaccine

ACIP recommends exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series. The fourth dose may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at 15-18 months.

Hepatitis A

Hepatitis A vaccine (Hep A) is listed on the schedule for the first time because it is recommended for routine use in some states and regions. Its appearance on the schedule alerts providers to consult with their local public health authority to learn the current recommendations for hepatitis A vaccination in their community. Additional information on the use of Hep A can be found in recently published guidelines (2).

Hepatitis B

Special considerations apply in the selection of hepatitis B vaccine products for the dose administered at birth (6).

Vaccine Information Statements

The National Childhood Vaccine Injury Act requires that all health-care providers, whether public or private, give to parents or patients copies of Vaccine Information Statements before administering each dose of the
vaccines listed in this schedule (except Hep A). Vaccine Information Statements, developed by CDC, can be obtained from state health departments and CDC's World-Wide Web site, http://www.cdc.gov/nip/publications/VIS.

Instructions on use of the Vaccine Information Statements are available from CDC's website or the December 17, 1999, Federal Register (64 FR 70914).

References

1. CDC. Recommended childhood immunization schedule--United States, 1999. MMWR 1999;48:12-6.
2. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(no. RR-12).
3. American Academy of Pediatrics. Active and passive immunization. In: Peter G, ed. 1997 Red book: report of the Committee on Infectious Diseases. 24th ed. Elk Grove Village, Illinois: American Academy of Pediatrics
1997:1-71.
4. CDC. Withdrawal of rotavirus vaccine recommendation. MMWR 1999;48:1007.
5. CDC. Recommendations of the Advisory Committee on Immunization Practices: revised recommendations for routine poliomyelitis vaccination. MMWR
1999;48:590.
6. CDC. Recommendations regarding the use of vaccines that contain thimerosal as a preservative. MMWR 1999;48:996-8.

* Use of trade names and commercial sources is for identification only and does not constitute or imply endorsement by CDC or the U.S. Department
of Health and Human Services.

- MMWR, January 21, 2000

II. FDA prescribes caution in use of flu fighter

The Food and Drug Administration, saying it has received reports of respiratory problems following use of the new inhaled flu medication Relenza, is advising doctors to use "special caution" when prescribing the drug to patients with asthma or chronic obstructive pulmonary disease. In a health advisory, the FDA said patients who have breathing problems should use Relenza only with careful supervision. The advisory also reminds doctors that flu vaccine is the first line of defense and that new anti-viral medications are not effective against bacterial infections.

- USA Today, January 13, 2000

III. Conference on Vaccine Research

The Third Annual Conference on Vaccine Research: Basic Science--Product Development--Clinical and Field Studies will be held April 30-May 2, 2000, in Washington, D.C. This conference is sponsored by the National Foundation for Infectious Diseases (NFID) in collaboration with CDC, the National Institute of Allergy and Infectious Diseases, the International Society for Vaccines, the Center for Biologics Evaluation and Research of the Food and Drug Administration, the World Health Organization, the Albert B. Sabin Vaccine Institute at Georgetown University, and the U.S. Department of Agriculture. The meeting covers scientific data and issues from the disciplines involved in the research and development of vaccines and associated technologies for the control of human and veterinary diseases through vaccination.

Program announcements and forms for abstract submission, registration, and hotel reservations are available from Kip Kantelo, NFID, Suite 750, 4733 Bethesda Ave., Bethesda, MD 20814-5228; telephone (301) 656-0003, ext. 19; fax (301) 907-0878; e-mail kkantel-@nfid.org; World-Wide Web site http://www.nfid.org/conferences/.*

IV. MMWR Summary of Notifiable Diseases, US 1998

The MMWR Summary of Notifiable Diseases, United States, 1998 contains summary tables of the official statistics for the reported occurrence of nationally notifiable diseases in the United States for 1998. These statistics are collected and compiled from reports to the National Notifiable Diseases Surveillance System (NNDSS), which is operated by CDC in collaboration with the Council of State and Territorial Epidemiologists (CSTE).

Because the dates of onset or diagnosis for notifiable diseases are not always reported, these surveillance data are presented by the week they were reported to CDC by public health officials in state and territorial health departments. These data are finalized and published each year in the MMWR Summary of Notifiable Diseases, United States for use by state and local health departments; schools of medicine and public health; communications media; local, state, and federal agencies; and other agencies or persons interested in following the trends of reportable diseases in the United States. This publication also documents which diseases are considered national priorities for notification and the annual number of cases of such diseases.

The Highlights section presents information on selected nationally notifiable and non-notifiable diseases to provide a context in which to interpret surveillance and disease-trend data and to provide further information on the epidemiology and prevention of selected diseases.

Background

As of January 1, 1998, a total of 52 infectious diseases were designated as notifiable at the national level. A notifiable disease is

one for which regular, frequent, and timely information regarding individual
cases is considered necessary for the prevention and control of the disease.

This section briefly summarizes the history of the reporting of nationally notifiable diseases in the United States.

Highlights for 1998

Diphtheria

One probable case of diphtheria was reported from Oregon in 1998. The case-patient had acute membranous pharyngitis. An oropharyngeal specimen was weakly positive for diphtheria toxin by polymerase chain reaction, but bacterial culture of the specimen was negative.

Outside the United States, more than 2,700 cases of diphtheria were reported in an epidemic in the Newly Independent States of the former Soviet Union (Dittmann S, Wharton M, Vitek C, et al. Successful control of
epidemic diphtheria in the Newly Independent States of the Former Soviet Union:
lessons learned in fighting public health emergencies. J Infect Dis 2000 [in press]). This epidemic has resulted in approximately 155,000 cases and
5,000 deaths since 1990. No importations into the United States were reported
in 1998.

Haemophilus influenzae, Invasive Disease

In 1998, a total of 255 cases of Haemophilus influenzae (Hi) invasive disease among children aged less than 5 years were reported (data were provided by the National Immunization Program and were based on date of onset, not MMWR week). Before a vaccine was introduced in 1987, approximately 20,000 cases of H. influenzae type b (Hib) invasive disease occurred among children annually (JAMA 1993;269:221-6). The sharp
decline in the number of Hib cases is attributed to the widespread use of the Hib vaccine among preschool-aged children. Of the 255 cases reported in
1998, a total of 197 (74%) Hi isolates were serotyped, and 61 (31%) of these
were type b. Among the 61 cases of Hib invasive disease reported in children
aged less than 5 years, 25 (41%) were among children aged less than 6 months,
which is too young to have completed a three-dose primary Hib vaccination.

However, 22 (61%) of the 36 children who were old enough (i.e., aged greater than or equal to 6 months) to have completed a three-dose primary series were incompletely vaccinated or their vaccination status was unknown.
These cases might have been prevented with age-appropriate vaccination.

Hepatitis A

In 1999, the Advisory Committee on Immunization Practices (ACIP) issued revised recommendations for the use of hepatitis A vaccine (HepA). Routine childhood HepA vaccination is recommended in states or counties/communities where the average annual hepatitis A virus (HAV) rate during 1987-1997 was approximately 20 cases 100,000 population (i.e., approximately twice the national average). In addition, routine childhood HepA vaccination can be considered in states or counties/communities where the average rate during 1987-1997 was at least 10 cases/100,000 population.

Of the 23,229 cases of HAV reported in 1998, approximately 60% originated from the 17 states affected by the ACIP recommendations. Eleven of these states had average rates of approximately 20 cases/100,000 persons during 1987-1997, and six states had average rates of approximately 10/100,000 during this period. However, these 17 states account for only 34% of the U.S. population.

Hepatitis B

The number of reported acute hepatitis B cases has decreased by more than 50% during the past decade, from 21,102 cases in 1990 to 10,258 cases in 1998. This downward trend is expected to continue as a national strategy for eliminating hepatitis B virus (HBV) transmission is implemented.
Components of this strategy include a) screening pregnant women for hepatitis B surface antigen (HBsAg) and providing postexposure immunoprophylaxis to infants of infected women; b) routinely vaccinating infants; c) providing catch-up vaccinations for children aged less than 19 years (particularly those aged 11-12 years); and d) targeting vaccinations to children, adolescents, and adults at increased risk for infection.

Draft Healthy People 2010 objectives emphasize the elimination of HBV transmission and include reducing the number of perinatal HBV infections to less than 400 and reducing the number of acute hepatitis B cases in persons aged 2-18 years to less than 10. Proposed age-specific target rates per 100,000
population for persons aged greater than 18 years are as follows: 3.2 cases/100,000 for persons aged 19-24 years, 11.1/100,000 for persons aged 25-39 years, and 1.0/100,000 for persons aged greater than or equal to
40 years.

Hepatitis C

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States (MMWR 1998;47[RR-19]). Based on data from CDC's sentinel counties viral hepatitis surveillance system, approximately 242,000 new HCV infections occurred each year during the 1980s. Since 1989, the annual number of new infections identified in the sentenial
counties has declined by 80%. For reasons that are unclear, this dramatic decline correlates with a decrease in cases among injecting-drug users (MMWR
1998;47[RR-19]). But in 1996, data from the Third National Health and Nutrition Examination Survey (1988-1994) indicated that approximately 4 million Americans (1.8%) have been infected with HCV. Most are chronically infected, although the majority might be unaware of their infection

because they are not clinically ill. Chronically infected persons can transmit
the virus to others and are at risk for chronic liver disease, including cirrhosis and liver cancer.

CDC guidelines for prevention and control of HCV infection and HCV-related chronic disease were published in October 1998 (MMWR 1998;47[RR-19]). The U.S. Food and Drug Administration also issued guidance in 1998 requiring the notification of persons who received blood or
blood products before July 1992 from donors subsequently found to be infected
with HCV. In May 1999, a national campaign was initiated to educate the public about hepatitis C and the need for persons at increased risk to be
tested.

These recommendations and activities are expected to increase the number of HCV-infected persons identified and reported to state and local health departments.

Lyme Disease

In 1998, a total of 16,801 cases of Lyme disease were reported, the highest number ever reported. This increase could be caused by an increase in human contact with infected ticks and enhanced reporting of cases.
Lyme disease occurs primarily in the northeastern and northcentral United
States.

The following nine states had incidence rates higher than the annual national average of 6.39 cases/100,000 population and accounted for 93.0% of reported cases: Connecticut (105.0/100,000), Rhode Island (79.6), New
York (25.5), New Jersey (24.0), Pennsylvania (22.9), Maryland (13.1), Massachusetts (11.5), Wisconsin (12.8), and Delaware (10.7).

In December 1998, a new Lyme disease vaccine was approved by the U.S. Food and Drug Administration. The Advisory Committee on Immunization Practices issued recommendations for use of this vaccine in June 1999 (MMWR 1999;48 [No. RR-7]). These recommendations emphasize that the decision
to vaccinate should be based on both geographic risk and individual exposure to tick-infested habitats. Because the Lyme disease vaccine is not 100% effective and does not protect against transmission of other tickborne
diseases, vaccinated persons should continue to practice personal protective measures against ticks and seek early diagnosis and treatment of
suspected tickborne infections.

Pertussis

On July 29, 1998, the fourth diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) was licensed for use in children aged 6 weeks-6 years. This vaccine is called Certiva,TM and it is manufactured
by North American Vaccine, Inc. Other DTaP vaccines licensed since 1996

include Tripedia[Registered] (Connaught Laboratories, Inc.), ACEL-IMUNE[Registered] (Lederle Laboratories Division of American Cyanamid Company), and Infanrix[Registered] (SmithKline Beecham Pharmaceuticals). The Advisory Committee on Immunization Practices recommends DTaP vaccines for all five doses in the childhood vaccination schedule.

Since 1980, the number of reported cases of pertussis has increased in the United States. The reasons for this rise are unknown, but could include increased awareness of pertussis among health-care providers, increased use of more sensitive diagnostic tests, and better reporting of cases to health departments. In 1998, a total of 24% of 7,405 reported cases occurred among children aged less than 7 months, who were too young to have received the recommended three doses of pertussis vaccine. Thirteen percent of cases were among preschool-aged children (i.e., those aged 1-4 years). Since 1995, the coverage rate with at least three doses of pertussis vaccine has been 95% among U.S. children aged 19-35 months. Twenty-six percent of cases were reported among children aged 10-19 years. Because vaccine-induced immunity wanes approximately 5-10 years after pertussis vaccination, adolescents can become susceptible to disease. Since 1990, the incidence among preschool-aged children has not changed, but the incidence among adolescents has increased in some states (Clin Inf Dis 1999;28:1230-7).

Poliomyelitis, Paralytic

As of January 1999, the Advisory Committee on Immunization Practices recommends only inactivated polio vaccine (IPV) for the first two doses of the polio vaccination series. Distribution of IPV as a proportion of overall polio vaccine use has increased from 6% in 1996 to 29% in 1997 to 34% in 1998. All six cases of vaccine-associated polio reported in the United States since January 1997 (including the single case reported in 1998) were associated with receipt of trivalent oral polio vaccine (OPV) for the first or second dose in an all-OPV schedule. An all-IPV schedule is recommended for routine childhood vaccination beginning January 1, 2000.

St. Louis Encephalitis

A summertime epidemic of St. Louis encephalitis in southern Louisiana accounted for 18 of the 24 cases reported nationally. No cases were fatal.

Culex pipiens quinquefasciatus was presumed to be the primary mosquito vector. The last major epidemic of St. Louis encephalitis in the United States (223 cases and 11 deaths) occurred in Florida in 1990. This disease occurs in portions of both the eastern and western United States.

Streptococcal Disease, Invasive, Group A

Nationally, approximately 10,200 cases of invasive group A streptococcal disease and 1,300 deaths occurred in 1998, according to reports from the Active Bacterial Core Surveillance (ABCS) project under

CDC's Emerging Infectious Diseases Program, which operates in seven states (California, Connecticut, Georgia, Maryland, Minnesota, New York, and Oregon). The incidence of this disease during 1998 was 3.8 cases/100,000 population. Rates were highest among children aged less than 1 year (7.5 cases/100,000) and adults aged greater than or equal to 65 years (10.0/100,000). Streptococcal toxic shock syndrome and necrotizing fasciitis each accounted for approximately 5.1% of invasive cases. The overall case-fatality rate among patients with invasive group A streptococcal disease was 12.2%.

Streptococcus pneumoniae, Drug-Resistant

During 1998, the Active Bacterial Core Surveillance (ABCS) project of CDC's Emerging Infectious Diseases Program collected information on invasive pneumococcal disease, including drug-resistant Streptococcus pneumoniae, in eight states -- California, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon, and Tennessee. Of 3,335 S. pneumoniae isolates collected during 1998, a total of 10.2% exhibited intermediate penicillin resistance (minimum inhibitory concentration [MIC] 0.1-1 ug/mL), and 13.6% were resistant (MIC greater than or equal to 2 ug/mL). For cefotaxime, 7.7% of all isolates had intermediate resistance (MIC 1 ug/mL), and 6.1% were resistant (MIC greater than or equal to 2 ug/mL). The proportion of isolates resistant to erythromycin was 14.7% (MIC greater than or equal to 2 ug/mL).

The overall proportions of isolates that were not susceptible to these three drugs were not substantially different compared with 1997 data. However, the proportions that were resistant varied widely among surveillance sites in 1998, and an increase in the prevalence of resistant strains, compared with earlier years, was reported from some states (data available at http://www.cdc.gov/ncidod/dbmd/abcs/survreports.htm).

Tetanus

The first case of neonatal tetanus reported in the United States since 1995 was reported from Montana in 1998. The case occurred in an infant born to a mother who was not immunized because of her philosophic beliefs and who used a nonsterile bentonite clay recommended by a lay midwife for the care of the baby's umbilical cord. The infant recovered after a 3-week hospitalization, including 12 days of mechanical ventilation. Of the 41 cases of tetanus that occurred in 1998, a total of 16 (39%) were among persons aged greater than or equal to 60 years, and 16 (39%) were among persons aged 20-59 years.

Varicella

Although varicella (chickenpox) deaths did not become nationally notifiable until January 1, 1999, some states began reporting varicella deaths to CDC during the second half of 1998. These data highlighted that both children and adults are continuing to die from a disease that is

now vaccine-preventable. During 1998, national coverage for varicella vaccine among children aged 19-35 months was 43%. Efforts to increase vaccination of susceptible children, adolescents, and adults should include educating health-care providers that deaths and severe morbidity from varicella
are preventable.

Surveillance for Potential Bioterrorism Agents

CDC established the Bioterrorism Preparedness and Response Program in January 1999 to improve the public health capability to detect and respond to biological and chemical terrorism. Members of this program are
working with the FBI and other federal agencies to develop an organized and
tiered response to suspect and confirmed biological events. The program focuses on state-level preparedness for early clinical and laboratory detection, which is essential to ensure a prompt response to a bioterrorist attack (e.g., providing prophylactic medicines or vaccines). Initial activities target critical agents that a) are associated with high case-fatality, b) can be disseminated to a large population, c) can cause social disruption because of public perception, and d) require special preparedness needs. These critical agents and their associated diseases include variola major (smallpox), Bacillus anthracis (anthrax), Yersinia pestis (plague), Francisella tularensis (tularemia), Clostridium botulinum (botulism), and the viral hemorrhagic fevers (e.g., arenaviruses and filoviruses).

Several other agents have been identified but require less broad-based preparedness efforts, including ones that cause foodborne and waterborne diseases. A critical element for preparedness is defining the natural epidemiology of diseases that can be caused by critical agents, including anthrax and plague, which are nationally notifiable diseases. The last case of naturally occurring anthrax in the United States was reported in
1992. In 1998, a total of 9 cases of plague among humans were reported in the
United States.

- MMWR, January 21, 2000

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> We are looking for immunization success stories to highlight in
> advocacy material. Please email Mitch Rothholz at
mc-@mail.aphanet.org
> with information.
>
> **********
> RESOURCES:
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APhA2000 - APhA's Annual Meeting: March 10-14, 2000, Washington, DC

IMMUNIZATION RELATED- PROGRAMS

- HHS Secretary Donna Shalala: Monday, March 13, 9:30-11:00am,APhA Second General Session

1-13

- Pneumonia: The Uphill Battle with Resistance: Saturday, March 11,
8-10:00am

- Vaccinations for High Risk Populations: Saturday, March 11,1-3:00pm

- Extraordinary Infections: A Focus on Bioterrorism: Saturday,March 11,
3:30am-5:30pm

- Building a Year-Round Immunization Program: Saturday, March 11,
3:30-5:30pm

- Immunization Licensing Partners Briefing (invitation only): Sunday, March 12, 11:30am-3:00pm

- Travel Vaccine Primer: Sunday, March 12, 3:00-5:00pm

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* Interested in Pediatric Immunization Delivery - contact John Bullock, RPh, PharmVac, Inc., pharmva-@aol.com

* Disposal System for Needles/ Syringes - easy to utilize - contact SCI - Sharps Compliance at 1-800-772-5657

* Immunization Action Coalition & the Hepatitis B Coalition
Web: http://www.immunize.org/

>
> Mitchel C. Rothholz, R.Ph.
> Deputy to the Executive Vice-President
> APhA
> 2215 Constitution Ave, NW
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> (202) 429-7549 FAX (202) 429-6300
> mc-@mail.aphanet.org
>

Prototype*

Immunization Protocol

Standing Vaccine Orders
Authority to Immunize
Authority to Initiate Immunization
Standing Prescription Order to Administer Immunizations

Addressee **Date**

(Name of Pharmacist), Pharmacy License #_____, acting as delegated agent for the undersigned physician, according to and in compliance with Article _____ of the _____ State Pharmacy Practice Act, may administer the medications listed below on the premises of the ABC Pharmacy [or elsewhere] and for a fee.

[If desired, the pharmacist's credentials and training for competence in immunization delivery can be described here.]

To protect people from preventable infectious diseases that cause needless death and disease, this pharmacist may administer the following immunizations to eligible infants, children, adolescents, and adult patients, according to indications and contraindications recommended in current guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control & Prevention (CDC) and other competent authorities:

- influenza vaccine
- pneumococcal vaccine
- hepatitis B vaccine
- hepatitis A vaccine
- tetanus-diphtheria toxoids (adult, Td)
- measles-mumps-rubella (MMR) vaccine
- varicella vaccine
- *Haemophilus influenza* type b (Hib) vaccine
- other vaccines licensed by the Food & Drug Administration, except:

[list those exceptions]

Other vaccines may be added to or deleted from this list by written supplementary instruction from the undersigned.

In the course of treating adverse events following immunization, this pharmacist is authorized to administer epinephrine (at a dose of approximately 0.01 mg/kg body weight; maximum of 0.5 mg per dose) and diphenhydramine (at a dose of approximately 1 mg/kg; maximum of 50 or 100 mg per dose) by appropriate routes pending arrival of emergency medical services. The pharmacist will maintain current certification in cardiopulmonary resuscitation.

In the course of immunizing, this pharmacist must maintain perpetual records of all immunizations administered. Before immunization, all vaccine candidates will be questioned regarding previous adverse events after immunization, food or drug allergies, current health, immunosuppression, recent receipt of blood or antibody products, pregnancy, and underlying diseases. All vaccine candidates will be informed of the specific benefits and risks of the vaccine offered. All vaccinees will be observed for a suitable period of time after immunization for adverse events.

All vaccinees will be given a written immunization record. The immunization will be promptly reported to the patient's primary-care provider by FAX or mail. The immunization will also be reported to appropriate county or state immunization registries.

The pharmacist will endeavor not to disrupt existing patient-physician relationships. The pharmacist will refer patients needing medical consultation to a physician. The pharmacist will make special efforts to identify susceptible people who have not previously been offered immunizations.

[Add other specific instructions appropriate to this scenario].

As the authorizing physician, I will review, on a quarterly basis, the activities of the pharmacist administering vaccines under this protocol.

The authorization shall be valid until two years from the date indicated above, unless revoked in writing sooner or unless extended in writing.

Physician Name: _____

Physician Signature: _____

Address: _____

City: _____ **State:** _____ **Zip:** _____

Medical License #: _____

* Adapt according to your state's laws and regulations before implementing.

Prototype*

Protocol for Management of Severe Allergic/Anaphylactic Reactions

If an allergic reaction to a medication occurs, the following standing orders will be used:

1. Procedures:
   - ✓ Be prepared to call 911.
   - ✓ Take a thorough history for allergies and prior adverse events before any immunization.
   - ✓ Allow adequate physical space for fainting or collapse without injury and to lay patient flat on a hard surface in the event cardiopulmonary resuscitation (CPR) is needed.
   - ✓ Maintain current competency in immunization; observe all vaccinees for a suitable period of time after immunization; remind vaccinees to report any adverse events to you.

2. Supplies to Stock:
   - ✓ Epinephrine USP, 1 mg/ml (1:1,000). May be in vials of solution, *Ana-Guard* syringes (in *Ana-Kits*), or in an *Epi-Pen*. If an *Epi-Pen* is to be used, at least two adult *Epi-Pens* and two *Epi-Pen Jrs.* will be available whenever immunizations are given.
   - ✓ Diphenhydramine liquid and injection
   - ✓ Blood-pressure cuff, pediatric and adult size, with stethoscope

3. Recognition of Anaphylactic Reaction:
   - ✓ Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.
   - ✓ Angioedema (swelling of the lips, face, throat)
   - ✓ Bronchospasm, shock

4. Emergency Treatment:
   - (a) If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph 4(g).
   - (b) If symptoms are generalized, activate the emergency medical system (EMS), (e.g., call 911) and call the consulting physician for instructions. This should be done by another person, while the immunizer treats and observes the patient.
   - (c) Administer epinephrine according to the dose in the table below, subcutaneously or intramuscularly. Site of administration can be the anterior thigh or deltoid muscle.
   - (d) Administer diphenhydramine by IM injection according to the dose in the table below. Do **NOT** administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.
   - (e) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep patient in supine position unless they are having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.
   - (f) If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5 to 20 minutes, depending on patient's response.
   - (g) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may reoccur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form.

Epinephrine Dosing

(Dosing by body weight is preferred)

Age Group	Weight (kg)*	Weight (lbs.)*	Epinephrine Dose (1mg/ml=1:1,000 w/v)
1-6 months	4-7	9-15	0.05 mg / 0.05 ml
7-18 months	7-11	15-24	0.1 mg / 0.1 ml
19-36 months	11-14	24-31	0.13 mg / 0.13 ml
37-48 months	14-17	31-37	0.16 mg / 0.16 ml
49-59 months	17-19	37-42	0.18 mg / 0.18 ml
5-7 years	19-23	42-51	0.2 mg / 0.2 ml
8-10 years	23-35	51-77	0.3 mg / 0.3 ml
11-12 years	35-45	77-99	0.4 mg / 0.4 ml
> 12 years	>45	>99	0.5 mg / 0.5 ml

Diphenhydramine Dosing

(Dosing by body weight is preferred)

Age Group	Weight (kg)*	Weight (lbs.)*	Diphenhydramine Dose (1mg/ml=1:1,000 w/v)
1-6 months	4-7	9-15	5 mg
7-18 months	7-11	15-24	10 mg
19-48 months	11-17	24-37	15 mg
4-7 years	17-23	37-51	20 mg
8-10 years	23-35	51-77	30 mg
11-12 years	35-45	77-99	40 mg
> 12 years	>45	>99	50 to 100 mg

*Weights reflect 50th percentile for corresponding ages.

Pharmacist's signature _____ Physician's signature _____ Date _____

Reference: Thibodeau JL. Office management of childhood vaccine-related anaphylaxis. Can Fam Phys 1994; 40:1602-10.

1-18

VACCINE ADMINISTRATION RECORD

Your pharmacist will keep this record in your medical file. Please complete the top portion of this form.

"I have read or have had explained to me written information about the vaccine listed below. I have had an opportunity to ask questions that were answered to my satisfaction. I understand the benefits and risks of the vaccine being administered and authorize the administration of the vaccine to me or to the person named below for whom I am authorized to make this decision."

Name: _____

Birthdate: _____ Gender: _____ SS#: _____

Allergies: _____

Doctor: _____

Medicare #: _____ Medicaid #: _____

Other Insurance: _____ Policy #: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

Signature of person to receive vaccine or person authorized to make the request (parent or guardian):

_____

For Clinic/Office Use:

Vaccine Name: _____ Manufacturer: _____

Lot Number: _____ Site of Injection: _____

Date Administered: _____

Vaccine Administrator: _____ Title: _____

Signature: _____

Clinic/Office Address: _____

City: _____ State: _____ Zip: _____

Adult Vaccine Administration Record

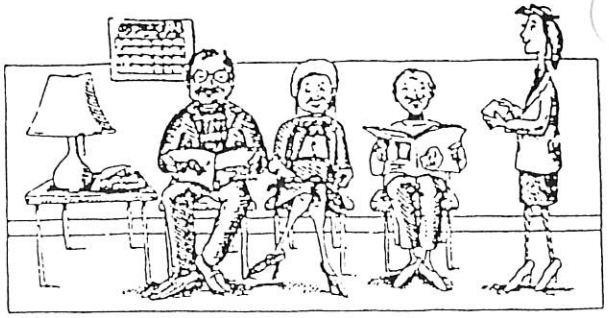
Patient name: _____

Birthdate: _____

Clinic chart number: _____

Vaccine administrator: Before administering any vaccines, make sure the person understands the risks and benefits of these vaccines and that their questions have been answered to their satisfaction. Make sure you give the patient an updated shot record card at every visit.

Vaccine and route	Date given mo/day/yr	Dose	Site given (RA, LA, RT, LT)	Vaccine lot number	Expiration date	Vaccine manufacturer	Signature or initials of vaccine administrator
DTP/DTaP/DT/Td - 1 (IM)							
DTP/DTaP/DT/Td - 2 (IM)							
DTP/DTaP/DT/Td - 3 (IM)							
DTP/DTaP/DT/Td - 4 (IM)							
DTP/DTaP/DT/Td - 5 (IM)							
Td booster (IM)							
Td booster (IM)							
Td booster (IM)							
Td booster (IM)							
Hepatitis B - 1 (IM)		mcg					
Hepatitis B - 2 (IM)		mcg					
Hepatitis B - 3 (IM)		mcg					
Hepatitis A - 1 (IM)							
Hepatitis A - 2 (IM)							
MMR - 1 (SQ)							
MMR - 2 (SQ)							
Varicella - 1 (SQ)							
Varicella - 2 (SQ)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Influenza (IM)							
Pneumococcal (IM or SQ)							
Other							
Other							
Other							
Other							



Your name: _____

Date of birth: mo _____ day _____ year _____

Today's date: mo _____ day _____ year _____

Screening Questionnaire for Adult Immunization

The following questions will help us determine which vaccines may be given in clinic today. Please answer these questions by checking the boxes. If the question is not clear, please ask the nurse or doctor to explain it.

	Yes	No	Don't Know
1. Are you sick today?	☐	☐	☐
2. Do you have allergies to medications, eggs, any vaccine, or any vaccine component?	☐	☐	☐
3. Have you ever had a serious reaction after receiving a vaccination?	☐	☐	☐
4. Do you, any person who lives with you, or any person you take care of have cancer, leukemia, AIDS, or any other immune system problem?	☐	☐	☐
5. Do you, any person who lives with you, or any person you take care of take cortisone, prednisone, other steroids, anticancer drugs, or x-ray treatments?	☐	☐	☐
6. During the past year have you received a transfusion of blood or plasma, or been given a medicine called immune globulin?	☐	☐	☐
7. For women: Is it possible that you are pregnant or may become pregnant in the next three months?	☐	☐	☐

Did you bring your immunization record card with you? yes ☐ no ☐

It is important for you to have a personal record of your shots. If you don't have a record card, ask your doctor or nurse to give you one! Bring this record with you to your clinic visits. Make sure your clinic records all your vaccinations on it.

1-21

Artwork courtesy of New York State Department of Health

Item #P4065 (2/97)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Servic

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

October 30, 1998

John A. Gans, Pharm.D.
Executive Vice President
American Pharmaceutical Association
2215 Constitution Avenue, NW
Washington, D.C. 20037

Dear Dr. Gans:

Thank you for sharing with the Centers for Disease Control and Prevention (CDC) the training materials for your educational program, *Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists*. Also, the information you presented on the American Pharmaceutical Association's (APhA) efforts to actively involve pharmacists in national vaccine efforts is valuable to my colleagues and me.

At your request, the CDC comprehensively reviewed the educational materials for *Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists*. The review showed the program to adequately address CDC's national vaccine standards and to appropriately prepare pharmacists to assist public health officials with vaccine delivery. Overall, the program is of high quality and we are pleased to recognize your efforts.

The development of these training materials was supported in part by funds provided by the CDC's National Immunization Program (NIP) under Cooperative Agreement No. U66/CCU312177 *Enhancing Partnerships with Private Sector Health Care Providers* and with the contribution of CDC personnel and materials. However, its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

I look forward to your continued involvement with immunization advocacy. Our combined efforts will help to advance public health.

Sincerely,

José F. Cordero, M.D.
Deputy Director
National Immunization Program

Enclosure

1-22

IMMUNIZATION STATES FOR PHARMACISTS
(as of August 1999)

Alabama
Alaska
Arkansas
California
Colorado
Delaware
Georgia
Idaho
Illinois
Indiana
Iowa
Kentucky
Michigan
Mississippi
Missouri
Nebraska
Nevada
New Mexico
North Carolina
Ohio
Oklahoma
Oregon
South Carolina
South Dakota
Tennessee
Texas
Utah
Virginia
Washington State
Wisconsin

WESLEY
Medical Center
550 North Hillside
Wichita, Kansas 67214-4976
Telephone 316/688-2468

February 4, 2000

Robert Haneke, PharmD, BCPS
President KPhA
Wesley Medical Center
Wichita, KS 67214

Dear Dr. Haneke,

Thank you for contacting me and allowing me to provide my input regarding the legislation pending for pharmacists working under protocol with physicians to provide immunizations. As Chairperson of the City Wide Immunization Task Force in Wichita, Kansas I feel that this is a worthwhile cause and am very excited about it.

This Task Force, which I Chair, is working on finding methods to improve our immunization rates, not only internally in our hospitals, but also outside our institutions in our communities. As you are well aware of, access to immunizations is a barrier to patients as well as a deterrent. I feel that this legislation will provide better access for all patients to acquire proper and timely immunizations. Over thirty other states, including those that surround Kansas, have similar legislation and have dramatically improved their individual state's immunization rates, with no reports of any adverse outcomes.

I work with pharmacists on a daily basis in my practice and feel that those properly trained, working with physician oversight, are well qualified to provide immunizations, as outlined in this legislation.

I fully support this legislation and am excited about the fact that the residents of the State of Kansas will have this opportunity available to them.

If I may be of any further assistance in this matter, please do not hesitate to contact me.

Thank you.

Respectfully,

Valerie C. Rohlman MD

Valerie C. Rohlman, MD
Board Certified Infectious Disease
Chair, Medical Performance Improvement Committee
President Elect, Medical Staff Executive Committee
Wesley Medical Center
Wichita, Kansas

1-24

February 4, 2000

Robert Haneke, PharmD, BCPS
President KPhA
Wesley Medical Center
Wichita, KS 67214

Dear Dr. Haneke,

Thank you for contacting me and allowing me to provide my input regarding the legislation pending for pharmacists working under protocol with physicians to provide immunizations. As a practicing Physician in the State of Kansas, I feel that this is a worthwhile cause and I am very excited about it.

Physicians in Kansas are constantly working on finding methods to improve our state's immunization rate, both urban and rural. As you are well aware of, access to immunizations is a barrier to patients as well as a deterrent. I feel that this legislation will provide better access for all patients to acquire proper and timely immunizations. Over thirty other states, including those that surround Kansas, have similar legislation and have dramatically improved their individual state's immunization rates, with no reports of any adverse outcomes.

I work with pharmacists on a daily basis in my practice and feel that those properly trained, working with physician oversight, are well qualified to provide immunizations, as outlined in this legislation.

I fully support this legislation and am excited about the fact that the residents of the State of Kansas will have this opportunity available to them.

If I may be of any further assistance in this matter, please do not hesitate to contact me.

Thank you.

Respectfully,

Donna E. Sweet, MD
FACP
Professor of Medicine, University of Kansas School of Medicine

February 4, 2000

Robert Haneke, PharmD, BCPS
President KPhA
Wesley Medical Center
Wichita, KS 67214

Dear Dr. Haneke,

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If I may be of any further assistance in this matter, please do not hesitate to contact me.

Thank you.

Respectfully,

Thomas A. Moore,, MD
Thomas A. Moore, M.D.
INFECTIOUS DISEASE SPECIALIST
IDC, PA
1100 N. St. Francis Suite 170
WICHITA KS 67214
316/264-3505

1-26

PHARMACISTS AS ADULT IMMUNIZERS: EFFECTS ON SITES & RATES OF VACCINE DELIVERY

John Douglas Grabenstein, RPh, PhD, FRSH
Lieutenant Colonel, United States Army

Doctoral Dissertation, 7 June 1999, UNC Schools of Pharmacy & Public Health, Chapel Hill, NC

Abstract

Pneumococcal disease and influenza are still the leading infectious cause of death in America. This group of studies evaluated the effect of vaccine administration by pharmacists on adult immunization rates. A historical review suggests four factors limited pharmacy's early involvement with vaccines: injection requirements, side-effect profile, government purchase, and government provision.

A cross-sectional study surveyed 1730 adults vaccinated at 21 pharmacies in 10 states, who traveled a median of 3 miles or 10 minutes. More than 96% of people vaccinated by a pharmacist were fully satisfied with the experience. Many vaccinees considered pharmacies advantageous, based on access, proximity, trust, convenience, or cost.

The primary component of this project was a cohort study to assess immunization coverage and vaccine-provider choice via a mailed survey. A cohort of 1004 adult prescription recipients in urban Washington State, where pharmacists administer vaccines, was contrasted with 1086 adults in urban Oregon, where pharmacists do not vaccinate.

Influenza vaccination rates were 7% higher in Washington than in Oregon in 1998, adjusting for baseline differences in 1997 ($p=0.05$). The proportion vaccinated among people younger than 65 years of age who received indicator prescriptions for chronic diseases (e.g., digoxin, insulin, theophylline) increased by 11% ($p=0.05$). Among people unvaccinated against influenza in 1997, the 1998 influenza vaccination rate was 35% in Washington and 24% in Oregon ($p = 0.01$).

More than 82% of adult prescription recipients returned to the same type of vaccine prescriber in consecutive years. Two distinct axes account for choices of vaccine provider: convenience and experience. Influenza vaccinations in physician offices in Washington increased during the time pharmacists began immunizing prescription recipients against influenza and pneumococcal disease, at a faster rate than in other settings. People are more likely to migrate from nontraditional to traditional vaccine providers than in the opposite direction.

People vaccinated by a pharmacist in these surveys were fully satisfied with the experience. Vaccine delivery by pharmacists is associated with higher rates of influenza vaccination, especially among people younger than 65 taking indicator medications and people previously unvaccinated. Vaccinations in physician offices increased during expansion of nontraditional vaccination programs in this setting.

EXECUTIVE SUMMARY

Increased delivery of pneumococcal and influenza vaccines is needed to avert tens of thousands of preventable deaths in the United States each year. This dissertation is comprised of three distinct studies of the role of pharmacists in adult vaccine delivery: a historical review, a

survey of people vaccinated in pharmacies, and a cohort study contrasting adult prescription recipients in Washington with a similar group in Oregon.

Vaccination in community pharmacies is a relatively new service that is expanding rapidly. If immunization delivery in physician offices, in public-health clinics, and from other providers is unimpaired by the introduction of pharmacists as vaccine providers, then net immunization rates against pneumococcal disease and influenza should increase. This step toward achieving national public-health goals will save lives. This scenario could constitute a success for pharmacy-based immunization delivery and could warrant replication of this approach to immunization delivery in other communities.

A. HISTORICAL REVIEW

A review of the history of pharmacists' involvement with vaccines and antibodies describes roles including storage, distribution, advocacy, and vaccine administration. Four primary factors seem to have limited pharmacy's early involvement with vaccines: the novel route of administration (i.e., injection), a daunting side-effect profile (e.g., anaphylaxis, serum sickness), collective (i.e., government) purchasing, and collective vaccine-delivery programs (e.g., in health centers). At the close of the 20th century, pharmacists are learning to vaccinate, encouraged by patients who appreciate this health service and by health officials who need additional vaccine providers to overcome shortfalls in immunization delivery.

B. CROSS-SECTIONAL STUDY

To describe the demographic, clinical, and attitudinal characteristics of people vaccinated by pharmacists, a cross-sectional survey was compiled of 1730 adults vaccinated by pharmacists at 21 community pharmacies in 17 cities in 10 states. The states included Alabama, Arkansas, Idaho, Iowa, Mississippi, Nebraska, Tennessee, Texas, Virginia, and Wisconsin. Vaccinees were queried regarding age, gender, and demographic characteristics; current medications and prescription-use patterns; distance traveled; and opinions about vaccine providers.

Survey respondents were fully satisfied with the experience. When asked if they were likely to get vaccinated in a pharmacy in the following year, 96.7% said yes. When asked if they would recommend that a friend needing an immunization get vaccinated in a pharmacy, 98.5% said yes. The average number of influenza vaccinations administered in 1998 at these pharmacies

was 394 (± 436) doses per site. Trained pharmacists can efficiently vaccinate large numbers of adults in the course of routine pharmaceutical care.

C. COHORT STUDY

To measure the association between availability of pharmacist-immunizers and overall adult immunization delivery, a cohort study was conducted, contrasting 1,004 adults in urban Washington State, where pharmacists administer vaccines, to 1,086 adults in urban Oregon, where pharmacists did not. Subjects were derived from a randomized cluster sample of patients of 24 community pharmacies belonging to a single chain, Fred Meyer Pharmacies. Eligibility was based on October 1998 prescription records suggesting need for pneumococcal and influenza vaccines.

Influenza vaccination rates were higher in settings where pharmacists immunize, than in settings where pharmacists did not immunize in 1998, adjusting for baseline differences in 1997. The proportion vaccinated in Washington was especially high among people younger than 65 years of age who received indicator prescriptions for chronic diseases (e.g., digoxin, insulin, theophylline), and among people unvaccinated against influenza in 1997. Vaccination was strongly associated with perceptions of vaccine benefit, convenience of vaccination, and severity and susceptibility to infection.

More than 82% of adult prescription recipients returned to the same type of vaccine prescriber in consecutive years. Two distinct axes account for choices of vaccine provider: convenience and experience. Influenza vaccinations in physician offices in Washington increased during the time pharmacists began immunizing prescription recipients against influenza and pneumococcal disease, both in absolute numbers and at a faster rate than in other settings. People are more likely to migrate from nontraditional to traditional vaccine providers than in the opposite direction. Choice of a traditional or nontraditional vaccine provider is strongly associated with where the person was vaccinated in the previous year, along with perceptions of proximity and experience of the provider.

Taken together, these studies suggest that society as a whole may benefit when pharmacists provide influenza and pneumococcal vaccines to adults. The people benefit from greater access to vaccinations. Pharmacists benefit from the opportunity to deliver needed preventive care. Other health-care providers stand to benefit from a general increase in interest and acceptance of adult vaccinations.

D. SUMMARY OF FINDINGS

D.1. **Survey respondents were fully satisfied with vaccinations administered to them by pharmacists.** Almost every respondent vaccinated by a pharmacist at the 21 pharmacies surveyed found the experience to be respectful and appropriate (Table 5.B.5, Table 5.B.9). A large proportion of the vaccinees considered the pharmacy to be advantageous, compared to other vaccine providers, on the basis of access, proximity, trust, convenience, or cost. Almost all (96.7%) would be willing to be vaccinated by a pharmacist in a subsequent year. Almost all (98.5%) would encourage a friend needing vaccination to visit his or her pharmacist.

D.2. **Pharmacists efficiently vaccinated large numbers of adults in the course of routine pharmaceutical care.** Pharmacists at 21 pharmacies delivered 8,266 influenza vaccinations between October and December 1998, with a mean of 394 doses per pharmacy and 212 doses per vaccinating pharmacist (Table 5.B.1a, Table 5.B.1b). Based on survey respondents, 28.4% of the people vaccinated by pharmacists were 65 years or older and 9.1% were younger than 65 taking medication for chronic heart or lung disease or diabetes (Table 5.B.3).

D.3. **In settings where pharmacists vaccinate, respondents younger than 65 with a chronic disease were more likely to be vaccinated against influenza.** The proportion vaccinated was 66.1% in Washington communities where pharmacists vaccinate, compared to 57.9% in Oregon communities ($p = 0.03$; Table 5.C.14). Perceptions of vaccine benefit, inconvenience of vaccination, and severity and susceptibility to infection are important covariates in their vaccination decisions (Table 5.C.21).

D.4. **In settings where pharmacists vaccinate, previously unvaccinated respondents are more likely to be vaccinated against influenza.** The proportions were 34.7% in Washington communities where pharmacists vaccinate, compared to 23.9% in Oregon (Table 5.C.22, $p = 0.01$). This association was observed both in those 65 years or older and in those younger than 65 with a chronic disease. In the cross-sectional study, 25.5% had not been vaccinated in the previous year (Table 5.B.2c) and 20.1% had not been vaccinated in either of the previous two years (Table 5.B.6). Perceptions of vaccine benefit, inconvenience of vaccination, and severity and susceptibility to infection are important covariates in their vaccination decisions (Table 5.C.26b).

D.5. **Respondents made vaccine-provider selection decisions on two major axes: (1) proximity-and-convenience and (2) experience-and-trust** (Table 5.D.3, Table 5.D.21, Table 5.D.24c). People who select nontraditional vaccine providers say that their vaccine provider was easier to get to, that it was closer, that they were planning to go there anyway, and that vaccines were offered at more convenient times. People vaccinated at traditional sites were more likely to say that their vaccine provider had more experience and that they trusted them more than other vaccine providers.

D.6. **Respondents tended to return to the same category of vaccine provider where they were vaccinated in the previous year**. This tendency of habit, ranging from 82% to 89%, was shown in the form of opinions (Section 5.C.3.h), knowledge (Table 5.D.1, Table 5.D.2), and behavior (Table 5.D.5, Table 5.D.11, Table 5.D.17, Table 5.D.24c). This finding reinforces the adage that "people are creatures of habit" in choice of where to be vaccinated.

D.7. **The number of adult influenza vaccinations in physician offices in Washington rose by 6.4% from 1997 to 1998,** during the period when pharmacists widely implemented influenza vaccination programs in their pharmacies (Table 5.D.9). In contrast, adult influenza vaccinations in physician offices in Washington rose by 3.1% during the same time interval, a significantly lower rate (RR = 2.1, 95% CI: 1.1, 3.9, $p = 0.02$).

D.8. **Respondents were more likely to migrate from nontraditional to traditional vaccine providers than in the opposite direction.** In Washington State, 25% of those vaccinated in a nontraditional setting in 1997 changed to a traditional setting in 1998, whereas 8% moved in the opposite direction ($p < 0.0001$) (Table 5.D.5). This effect also holds true comparing physician offices to all other vaccine providers, traditional and nontraditional. In Washington States, 29% of those vaccinated somewhere other than in a physician office in 1997 changed to a physician office in 1998, whereas 12% moved in the opposite direction ($p < 0.0001$) (Table 5.D.11).

E. STRENGTHS OF THIS STUDY

The major advantage of this group of studies is providing an assessment of typical vaccination practices, rather than a contrived experiment. Chapter 5-B is the most comprehensive description of people vaccinated in pharmacies undertaken to date. Chapter 5-C is likely to be the

first to evaluate the net effect on vaccine delivery of offering immunizations in pharmacies by pharmacists. Chapter 5-D is one of the first studies to analyze vaccine-provider choice criteria among adults. These studies measured rates of both pneumococcal and influenza immunization, among both young and elder adults with risk factors warranting immunization against these lethal infections.

Our study design provides comparable control and intervention groups by employing both an internal historical control (1997 vs. 1998 immunization behavior in Washington State) and a contemporaneous control group (1998 immunization behavior in Washington State vs. Oregon). Our approach discerns immunizations delivered at multiple sites in the course of standard practice, rather than in an atypical research setting.

The design selected may be one of the most conservative tests of the effect of pharmacists as immunizers. Prescription recipients, by definition, have access to a professional capable of providing vaccines, their physician. The communities studied generally had many sources of adult vaccine delivery and extensive networks of health insurance. Effects observed in other populations or environments with less access to vaccine delivery may be different, perhaps greater. Many of the respondents in Washington State indicated that their choice of vaccine provider was limited by their health insurance plan. For Washington pharmacists to have administered almost a quarter of the influenza vaccinations to these subjects in 1998 (Table 5.D.15) is remarkable.

Despite the limitations of any observational study, this study advances knowledge of adult immunization delivery patterns. This study measures immunization delivery at multiple health-care sites among two distinct populations. Immunization delivery to adults younger than 65 taking indicator medications has been poorly studied to date.

The findings of this study are consistent with previous studies (Huff *et al.*, 1982; Spruill *et al.*, 1982; Morton *et al.*, 1988; Williams *et al.*, 1987; Grabenstein & Hayton, 1990; Grabenstein *et al.*, 1993; Ernst *et al.*, 1997), showing pharmacists to be capable of both identifying and motivating patients at risk of influenza to be vaccinated.

This study identified three infection-and-immunization opinion factors that were consistent with factors identified in a similar survey among prescription recipients in Durham County, North Carolina, in 1991 (Grabenstein, 1991a). The factors identified in the 1999 survey parallel the 1991 study's findings, which included factors labeled "Vaccine Benefit" (the antithesis of "more trouble than it is worth"), "Accessibility" (the antithesis of "inconvenient"), and "Susceptibility & Severity."

F. LIMITATIONS OF THIS STUDY

F.1 Threats to Validity

The greatest limitation of this study is its reliance on respondents' own reports of vaccination status, date, and location. This is especially problematic for the recall of pneumococcal immunization long ago.

Because this was an observational study, subjects were not randomly assigned to treatment or control groups. Nonetheless, identical selection criteria were used in the Washington and Oregon cohorts. The pharmacies in these two states were part of a single chain of pharmacies. Comparable distribution of demographic and clinical parameters between the two groups was documented based on prescription databases and survey responses. Washington communities had higher median incomes and greater ethnic diversity than Oregon communities, but these differences did not contribute to logistic-regression models of either vaccine acceptance or vaccine-provider choice.

Despite the demonstrated validity of the indicator medications used in this study to identify need for immunization (Grabenstein & Hayton, 1990), an automated prescription record is not equivalent to a clinical diagnosis. But given the high positive-predictive value of the indicator medications used in this study, this method has great utility.

F.1.a. Selection Bias

Subjects who were vaccinated but did not return their survey were not recorded as being vaccinated. The survey response rate after the third mailing was 52.4% (Table 5.C.2). If vaccine acceptors undetected by this survey are not differentially distributed between the cohorts, the effect would tend to bias our results toward the null, resulting in an underestimate of the pharmacy effect. If unrecognized vaccine acceptors are differentially distributed in such a way that the Washington group tended to contain more hidden acceptors than in Oregon, the effect would again be that of underestimation of the pharmacy effect. In the event that unrecognized vaccine recipients were higher in the Oregon group, we may have overestimated the pharmacy effect. We have no reason to believe that there would be a survey-response differential between the state cohorts. Surveys received were no more likely to come from Washington than from Oregon (Table 5.C.2).

Because the survey cover letter was printed on pharmacy stationary, there may have been a tendency for people who were vaccinated to respond more than people who declined vaccine. Decliners may be reluctant to report their declinations. Response bias of this type was observed in the Durham County, NC, study of prescription recipients (Grabenstein, 1991; Grabenstein *et al.*, 1993), and in Hutchison's Canadian study (1989a).

If nonrespondents to the survey select vaccine providers using different criteria than respondents, then observed immunization rates may not reflect the true population parameter.

F.1.b. Misclassification

Misclassification of vaccine provider may affect the proportions of some of the less common vaccine providers. For example, in the Pacific Northwest, many supermarkets and grocery stores contain pharmacies. People who named supermarkets as sources of vaccination may have been naming a pharmacist-administered vaccination site. Based on marginal comments by survey respondents, the hospital category may have included more people vaccinated on an occupational basis than people vaccinated as patients.

Some medications may be prescribed to patients for a use that does not warrant vaccination against influenza and pneumococcal disease. For example, if digoxin is prescribed to a patient who is merely hypertensive, the patient would be included in this study without substantial underlying need of vaccination. Our findings might be overestimates of a pharmacy-advocacy effect if this bias is substantial.

Some survey respondents to whom the computer attributes use of a drug may not actually be receiving it. For example, data-entry errors may misattribute some medication use to irrelevant patients. The most common form would likely be misattribution among patients with common names or parents and offspring with the same names. This effect should not be differential among the groups. No known errors of this type were identified.

A single pharmacy chain was selected as the study base to minimize interaction of selection biases and the experimental variable as a threat to external validity. The pharmacy executive of this chain permitted the researchers access to prescription records across the chain, minimizing any volunteer effect at the individual store level. Selection bias is also minimized by restricting pharmacy eligibility to chain pharmacies with the same chain being used in each state. In this regard, patients may be somewhat more homogeneous than the general population of the study areas. The use of a single chain would thus be expected to strengthen internal validity at the possible expense of decreasing generalizability.

F.2. Generalizability

The populations surveyed are limited in their representativeness of other populations. Elderly users of prescription medications are only partially representative of elderly people in general. For example, we have not assessed whether elderly prescription recipients are more or less impaired in their ability to travel to be vaccinated, compared to other seniors. People younger

than 65 years old with a chronic disease may have different perceptions of their need for vaccination, compared to either young adults without chronic disease or people 65 years or older.

G. FUTURE DIRECTIONS

This study was undertaken early in the process of training pharmacists as immunization providers and informing the public about vaccine availability from pharmacists. This study does not evaluate the longitudinal effect of pharmacists on immunization delivery beyond this two-season interval. Additional studies might address questions of how vaccine-provider choices change over time, as perceptions of the demarcation between "traditional" and "nontraditional" sources of vaccine change.

Because this study focuses on prescription patients of a single large pharmacy chain, the study should be replicated in a mixture of chain and independent pharmacies and in other geographic settings to assess any differences in patient characteristics or public response. Other types of communities of interest would include minority communities, rural communities, and those with inadequate networks of health insurance.

Additional research is needed to discern the proportion of people who are vaccinated by pharmacists who have not seen a physician as an inpatient or an outpatient in the previous few years. Such studies might assess the rate at which pharmacists refer people to see physicians for further care.

Fred Meyer's vaccination program focused on influenza, with marginal attention paid to the delivery of pneumococcal vaccine. Nonetheless, pharmacists were the second most common site of pneumococcal vaccination in 1997 in Washington communities studied. Studies with more subjects vaccinated against pneumococcal disease are needed to determine whether influenza-vaccine site choices differ from pneumococcal-vaccine site choices.

Distance traveled to be vaccinated was larger in some settings than in others. The effect of the number of options for vaccine availability in relation to distance from a person's home or work setting is worthy of additional study, especially in rural settings where options for access to vaccine providers are more limited than in urban settings.

Despite the pretesting of the survey instrument, several improvements could be made in future studies to increase the instrument's precision. For example, the question "Do you consider this pharmacy to be your 'regular pharmacy'?" may elicit information about pharmacy loyalty. Questions about vaccination locations should be worded to distinguish people who are vaccinated there on an occupational basis. Further, the distinctions between mercantile locations that sell

groceries, merchandise, medical sundries, and prescriptions is blurring. In many cities in our study, most grocery stores include a pharmacy. But whether the public would refer to these institutions as markets or pharmacies in a survey is unknown. Future surveys might be worded more specifically to avoid this imprecision.

Multiple studies have now shown that pharmacists can deliver hundreds or thousands of doses of influenza and pneumococcal vaccines per pharmacy during influenza-vaccination season, in the course of their traditional prescription-dispensing role (Ernst *et al.*, 1997; Grabenstein, 1998a; Grabenstein, 1998b). Pharmacists can identify adults who need to be immunized (Grabenstein & Hayton, 1990) and persuade them to be immunized (Grabenstein *et al.*, 1993). Adults are willing to be immunized in their pharmacy by their pharmacist (Ernst *et al.*, 1997).

Immunizing pharmacists do not appear to reduce the number of vaccinations delivered by other vaccine providers. Indeed, vaccine-advocacy by pharmacists may be raising public consciousness of the value of influenza vaccination and leading to more people being vaccinated in their physician's office. The pool of unvaccinated adults is so large, tens of millions of Americans, that a variety of sources of adult vaccines is needed to reach the diversity of the public. Each vaccine-preventable death due to pneumococcal disease and influenza is a preventable tragedy.

Vaccination of adults by pharmacists is in the public interest. American public-health leadership should explicitly encourage vaccinations by pharmacists.

ACKNOWLEDGEMENTS:

Various components of these studies were funded by the United States Army Medical Department, the U.S. Agency for Health Care Policy & Research (AHCPR), and the American Pharmaceutical Association (APhA) Foundation.

I am grateful to Fred Meyer pharmacists for their contributions to vaccine delivery among their patients and to the Fred Meyer corporate leadership for their collaboration in this research.

PHARMACISTS AS ADULT IMMUNIZERS: EFFECTS ON SITES & RATES OF VACCINE DELIVERY

John Douglas Grabenstein, RPh, PhD, FRSH
Lieutenant Colonel, United States Army

Doctoral Dissertation, 7 June 1999, UNC Schools of Pharmacy & Public Health, Chapel Hill, NC

Short Abstract

A cross-sectional study surveyed 1730 adults vaccinated by pharmacists at 21 pharmacies in 10 states. More than 96% were fully satisfied. Many vaccinees considered pharmacies advantageous for access, proximity, trust, convenience, or cost.

Second, we conducted a cohort study to assess immunization coverage and vaccine-provider choice via a mailed survey. A cohort of 1004 adult prescription recipients in urban Washington State, where pharmacists administer vaccines, was contrasted with 1086 adults in urban Oregon, where pharmacists do not vaccinate.

Influenza vaccination rates were 7% higher in Washington than in Oregon in 1998, adjusting for baseline differences in 1997 ($p=0.05$). The proportion vaccinated among people younger than 65 years of age who received indicator prescriptions for chronic diseases increased by 11% ($p=0.05$). Among people unvaccinated in 1997, the 1998 influenza vaccination rate was 35% in Washington and 24% in Oregon ($p = 0.01$).

More than 82% of adult respondents returned to the same type of vaccine prescriber in consecutive years. Two distinct axes account for choices of vaccine provider: convenience and experience. Influenza vaccinations in physician offices in Washington increased during the time pharmacists began immunizing adults. People are more likely to migrate from nontraditional to traditional vaccine providers than the opposite.

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Testimony presented to
Senate Committee on Public Health and Welfare by
Sally Finney, Executive Director on
March 16, 2000

Thank you, Chairman Praeger and members of the committee, for allowing me to appear before you today. I am here on behalf of the members of the Kansas Public Health Association to ask your support of House Bill 2759.

Since vaccine technology first became available in the last century, immunizations have been an integral part of public health. I have attached to my testimony a list of leading causes of death among Kansans in the year 1900. Influenza/pneumonia, diphtheria, typhoid fever, measles, and whooping cough ranked second, seventh, eighth, ninth, and tenth, respectively. All of these are vaccine-preventable diseases. For comparison, I have provided a list of causes of death for the year 1998, shown on the reverse side. Influenza/pneumonia ranked as the fifth leading cause of death among Kansans, and, in fact, ranks as the sixth leading cause nationwide. Although this bill does not limit itself to immunization of adults against influenza and pneumonia, it is on these two diseases which can pose such a serious threat to the health of adults that I will focus my remarks.

Although the technology exists to prevent these serious health threats, many adults fail to take advantage of it. Public health has learned over time that for disease prevention efforts to succeed, we must reach the target audience by bringing the intervention to them. That is why we believe HB 2759 makes sense. Those who are at greatest risk for death from complications resulting from influenza and pneumonia are older adults. These individuals generally have access to the local pharmacy where they could, under the provisions of this legislation, ask a trained pharmacist to administer immunizations. The training and education requirements that will apply to pharmacists under HB 2759 help to assure proper handling and administration of vaccine.

We believe that allowing pharmacists to administer immunizations is a positive step towards reducing serious health complications and deaths from vaccine-preventable disease in Kansas. This not only includes influenza and pneumonia but other infections such as tetanus and hepatitis B. That is why KPHA also asks that you not amend HB 2759 to limit its scope to just influenza and pneumonia.

Again, I ask your support of HB 2759. Thank you for your time.

Senate Public Health and Welfare
Date: 3-16-00
Attachment No. 2

Leading Causes of Death in Kansas

1900

1. Heart and kidney diseases
2. Influenza and pneumonia
3. Tuberculosis
4. Gastritis, duodenitis, enteritis, and colitis
5. All other causes
6. Cancer
7. Diphtheria
8. Typhoid fever
9. Measles
10. Whooping cough

Source: Kansas Department of Health and Environment, Office of Health Care Information

Leading Causes of Death in Kansas

1998

1. Heart disease
2. Cancer
3. Stroke
4. Chronic obstructive pulmonary disease
5. Influenza and pneumonia
6. Diabetes mellitus
7. Motor vehicle accidents
8. All other accidents
9. Suicide
10. Kidney disease

Source: Kansas Department of Health and Environment, Office of Health Care Information

KMS

KANSAS MEDICAL SOCIETY

TO: Senate Committee on Public Health and Welfare

FROM: Chris Collins Chris Collins
Director of Government Affairs

DATE: March 16, 2000

RE: HB 2759; Vaccinations by Pharmacists

The Kansas Medical Society appreciates the opportunity to appear today to testify on HB 2759, which amends the Pharmacy Act to permit pharmacists to administer vaccine pursuant to a written protocol by a physician.

The bill presents a bit of a dilemma for us. KMS supports efforts to improve vaccination rates across the population. It is well established that improved rates of vaccinations will help prevent illness. However, we do have reservations about this bill.

First, is there truly a need for this change? Have the bill's proponents really established that adult Kansans do not already have adequate access to vaccinations? Physicians' offices, hospitals and public health clinics all currently provide vaccinations at nominal cost. Will this change really improve vaccination rates, or will it just further fragment care?

Nonetheless, if this committee does feel this change is necessary, then the bill does protect the patient by ensuring that pharmacists would at least receive some training on the proper administration of vaccinations, something that the pharmacist curriculum completely lacks right now. Patients are further protected by ensuring that vaccinations are administered only pursuant to a physician protocol. However, the bill does not limit the types of vaccinations that pharmacists would be authorized to provide. You have doubtless heard testimony today that the public policy concern driving this bill is increased access for seniors to flu and pneumonia shots. Thus, we would respectfully urge this committee to adopt the attached balloon amendment that clarifies this point. Our members have expressed reservations about pharmacists administering other vaccinations, such as for hepatitis, because they carry greater risk of adverse reactions.

This bill also raises the specter of future scope of practice concerns. Is this just the first step in pharmacists' wanting to expand pharmacy practice to include operating primary care clinics? What will be next?

In summary, KMS agrees with the philosophy driving this bill, namely, that vaccines should be readily available to all Kansans. However, we would respectfully urge the adoption of the attached amendment. Thank you for your attention today on this important issue.

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Senate Public Health and Welfare
Date: 3-16-00
Attachment No. 3

3-8

Session of 2000

HOUSE BILL No. 2759

By Committee on Health and Human Services

1-31

AN ACT relating to the pharmacy act of the state of Kansas; authorizing pharmacists to administer drugs under certain conditions; amending K.S.A. 1999 Supp. 65-1626 and 65-1626a and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 1999 Supp. 65-1626 is hereby amended to read as follows: 65-1626. For the purposes of this act:

(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner; ~~or~~;

(2) the patient or research subject at the direction and in the presence of the practitioner; *or*

(3) a pharmacist.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(c) "Board" means the state board of pharmacy created by K.S.A. 74-1603 and amendments thereto.

(d) "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name than the brand name drug product prescribed.

(e) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

(f) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

(g) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to pa-

tients, and complete the final check before dispensing.

(h) "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner.

(i) "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

(j) "Distribute" means to deliver, other than by administering or dispensing, any drug.

(k) "Distributor" means a person who distributes a drug.

(l) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, as defined in K.S.A. 47-501 and amendments thereto, if such livestock remedy has been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated.

(m) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(n) "Generic name" means the established chemical name or official name of a drug or drug product.

(o) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

(A) Inmates of a jail or correctional institution or facility;

(B) residents of a juvenile detention facility, as defined by the Kansas code for care of children and the Kansas juvenile justice code;

(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas; or

(D) employees of a business or other employer.

(2) "Institutional drug room" does not include:

(A) Any registered pharmacy;

(B) any office of a practitioner; or

(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or

administered.

(p) "Medical care facility" shall have the meaning provided in K.S.A. 65-425 and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b and amendments thereto except community mental health centers and facilities for the mentally retarded.

(q) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by: (1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice; (2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or (3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(r) "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

(s) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(t) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(u) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either

in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

(v) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.

(w) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

(x) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

(y) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

(z) "Prescription" means, according to the context, either a prescription order or a prescription medication.

(aa) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

(bb) "Prescription-only drug" means any drug whether intended for use by man or animal, required by federal or state law (including 21 United States Code section 353, as amended) to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.

(cc) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner or mid-level practitioner.

(dd) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or permit of a business or profession for which a license, registration or permit

is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

(ee) "Professional incompetency" means:

(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(ff) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a prescription-only drug; or (3) a drug intended for human use by hypodermic injection.

(gg) "Secretary" means the executive secretary of the board.

(hh) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 65-1654 and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

(ii) "Mid-level practitioner" means an advanced registered nurse practitioner issued a certificate of qualification pursuant to K.S.A. 65-1131 and amendments thereto who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-1130

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and amendments thereto or a physician's assistant registered pursuant to K.S.A. 65-2896a and amendments thereto who has authority to prescribe drugs pursuant to a written protocol with a responsible physician under K.S.A. 65-2896e and amendments thereto.

(jj) "Vaccination protocol" means a written protocol, agreed to by a pharmacist and a person licensed to practice medicine and surgery by the state board of healing arts, which establishes procedures and recordkeeping and reporting requirements for administering a vaccine by the pharmacist for a period of time specified therein, not to exceed two years.

Sec. 2. K.S.A. 1999 Supp. 65-1626a is hereby amended to read as follows: 65-1626a. (a) For the purpose of the pharmacy act of the state of Kansas, the following persons shall be deemed to be engaged in the practice of pharmacy:

(1) Persons who publicly profess to be a pharmacist, or publicly profess to assume the duties incident to being a pharmacist and their knowledge of drugs or drug actions, or both;

(2) persons who attach to their name any words or abbreviation indicating that they are a pharmacist licensed to practice pharmacy in Kansas.

(b) "Practice of pharmacy" means the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; *the administering of vaccine pursuant to a vaccination protocol;* the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of prescription drugs and prescription devices and the maintenance of proper records thereof in accordance with law; consultation with patients and other health care practitioners about the safe and effective use of prescription drugs and prescription devices; and participation in the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy. Nothing in this subsection shall be construed to add any additional requirements for registration or for a permit under the pharmacy act of the state of Kansas or for approval under subsection (g) of K.S.A. 65-1643 and amendments thereto, or to prevent persons other than pharmacists from engaging in drug utilization review, or to require persons lawfully in possession of prescription drugs or prescription devices to meet any storage or record keeping requirements except such storage and record keeping requirements as may be otherwise provided by law or to affect any person consulting with a health care practitioner about the safe and effective use of prescription drugs or prescription devices.

New Sec. 3. (a) A pharmacist may administer vaccine to a person 18 years of age or older pursuant to a vaccination protocol if the pharmacist

influenza or pneumonia

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has successfully completed a course of study and training, approved by the American council on pharmaceutical education or the board, in vaccination storage, protocols, injection technique, emergency procedures and recordkeeping. A pharmacist who successfully completes such a course of study and training shall maintain proof of completion and, upon request, provide a copy of such proof to the board.

(b) A pharmacist may not delegate to any person the authority granted under this act to administer a vaccine.

(c) This section shall be a part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 4. K.S.A. 1999 Supp. 65-1626 and 65-1626a are hereby repealed.

Sec. 5. This act shall take effect and be in force from and after its publication in the statute book.

KANSAS
DEPARTMENT OF HEALTH & ENVIRONMENT
BILL GRAVES, GOVERNOR
Clyde D. Graeber, Secretary

March 16, 2000
Senate Public Health and Welfare Committee
House Bill 2759

Testimony presented by:

Gianfranco Pezzino, MD, MPH
State Epidemiologist, Director
Bureau of Epidemiology and Disease Prevention

The Kansas Department of Health and Environment looks with interest at any initiative aimed at improving the immunization coverage of adults in our state. While great progress in our state and in the country as a whole has been achieved in improving immunization coverage among children, too many adults still do not receive the immunizations they need. For example, a survey carried out by our agency in 1997 revealed that only less than 35% of adults interviewed had received a flu vaccine. In addition to influenza vaccine, other vaccines highly recommended for all adults or for some high risk groups are pneumococcal (to protect against invasive pneumonia), diphtheria, and tetanus.

HB 2759 has the potential to expand adult immunization by making vaccines more easily accessible, which can be a serious barrier particularly in rural settings. According to information from the American Pharmaceutical Association, at least 22 states allow pharmacists to administer vaccines. We have personally verified that pharmacists can administer immunizations in Missouri, Nebraska, and Oklahoma. In Colorado, immunizations are administered in drugstores by nurses. My conversations with colleagues in states where pharmacists have been allowed to administer immunizations revealed that overall no major problems were encountered and people seem satisfied that such projects have made vaccines more easily available to the public.

One issue we would like to bring to your attention is that accurate record keeping to show what vaccines each individual has received is essential to assure that the proper individuals are vaccinated and to prevent the administration of unnecessary vaccinations to individuals already immunized. This bill refers the definition of the record-keeping and reporting requirements to vaccination protocols to be developed and renewed every two years. Some vaccines in adults are administered every five or ten years (or sometimes even only once or twice in the lifetime). We would like to make sure that the standards adopted in these protocols are equivalent to those in place in private medical practices, where immunization records are usually retained for at least ten years, and sometime indefinitely. Other issues to consider related to record keeping are whether pharmacists will forward a notice regarding the

vaccination to the "medical home" of each individual they immunize and whether a pharmacist would be able to access medical records containing information on previous immunizations received by an individual.

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Kansas Academy of Family Physicians

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March 13, 2000

To: Senate Public Health & Welfare Committee
RE: Vaccinations by Pharmacists, HB 2759

Thank you for the opportunity to present written testimony on HB 2759. My name is Keith Wright. I am a family physician in Manhattan, and I represent the Kansas Academy of Family Physicians, which has over 1,430 members across the state. I serve as president of the KAFP this year. I am writing to express our members' views on House Bill 2759 on vaccinations by pharmacists.

We fully support efforts to improve vaccination rates. But we have concerns about this bill, and don't believe it's the way to do so. The concerns relate to the need for a change; comprehensive care, documentation, continuity, long term follow-up; and scope of practice.

Why is there any need for a change? Is there really an access issue? Adult Kansans already have adequate access to vaccinations through physicians' offices, hospitals, and public health clinics. We don't believe it will improve vaccination rates, nor do we believe there is a vaccination access issue for adults.

Are pharmacists prepared to provide all immunizations? How will they deal with long term care and documentation? Patients often forget and need to be reminded. This needs to be coordinated by those providing longitudinal care. And what about any adverse reactions? We believe the best place for Kansans to receive their health care is through a well-trained physician who provides comprehensive, continuity of care with long term follow-up. The concept of a "medical home" is the best model for health care. This bill simply fragments health care.

Finally, this bill also raises the question of scope of practice concerns in the future. Is it the first step towards expansion of pharmacy practice to include more primary care, and even primary care clinics?

In summary, we don't believe there is an access issue, nor that this bill would solve the issue if there was one. It only serves to further fragment health care. Thank you again for the opportunity to introduce testimony. Feel free to contact me if you have questions.

Sincerely,

Keith A. Wright MD

Keith Wright, MD
President

Senate Public Health and Welfare
Date: 3-16-00
Attachment No. 5