

Appendix 2.3

CHRONOLOGICAL INTRODUCTION OF TYPES OF VACCINE PRODUCTS THAT ARE STILL LICENSED IN THE UNITED STATES

The year of introduction of each of **49** of the **51** types of vaccine products currently licensed in the United States, along with the manufacturing establishment with the oldest license still in effect for each product, is shown in table 2.3 A.] For 42 (86 percent) of these 49 products, the establishment that received the original product license still holds this license. As

¹Only 49 of the currently licensed 51 types of licensed products are included. Polyvalent bacterial antigens with "no U.S. standard of potency" and polyvalent bacterial vaccines with "no U.S. standard of potency" are excluded.

shown in table 2.3B, American pharmaceutical companies were issued 37 (89 percent) of the original licenses for these 42 products. New or improved types of products that are currently licensed have been introduced at a fairly consistent rate of three to seven products per each 5-year interval since 1940.² Ten of the currently licensed products were licensed before **1940**.

²The number of currently licensed vaccine products introduced in the United States in 5-year intervals since 1940 is shown in table 5 in ch. 2.

Table 2.3A—Chronological Introduction of Types of Vaccine Products Still Licensed in the United States

Year	Type of vaccine product	Establishment with oldest product license still in effect ¹
1903	Diphtheria antitoxin	Massachusetts Public Health Biologic Laboratories (191 7)
1907	Tetanus antitoxin	Parke, Davis and Company (191 5)
1914	Pertussis vaccine	Lederle Laboratories
	Typhoid vaccine	Massachusetts Public Health Biologic Laboratories (191 7)
	Rabies vaccine	Eli Lilly and Company*
1917	Cholera vaccine	Eli Lilly and Company*
1926	Diphtheria toxoid	Parke, Davis and Company (1927)
1933	Staphylococcus toxoid	Lederle Laboratories*
	Tetanus toxoid	Merck Sharp and Dohme
1941	Typhus vaccine	Eli Lilly and Company
1942	Plague vaccine	Cutter Laboratories*
	Rocky Mountain Spotted Fever vaccine	Lederle Laboratories*
1945	Influenza virus vaccine	Lederle Laboratories Merck Sharp and Dohme Parke, Davis and Company *
1946	Diphtheria and tetanus toxoids and pertussis vaccine adsorbed	Parke, Davis and Company •
1947	Diphtheria and tetanus toxoids	Parke, Davis and Company (1949)
1948	Diphtheria and tetanus toxoids and pertussis vaccine	Parke, Davis and Company (1952)
	Diphtheria and tetanus toxoids adsorbed	Parke, Davis and Company*
	Diphtheria toxoid adsorbed	Parke, Davis and Company*
1949	Pertussis vaccine adsorbed	Parke, Davis and Company (1952)
	Gas gangrene polyvalent antitoxin	Lederle Laboratories •
	Tetanus toxoid adsorbed	Parke, Davis and Company (1952)
1950	BCG vaccine	University of Illinois ²
1951	Antirabies serum	Lederle Laboratories ²
1953	Yellow Fever vaccine	Connaught Laboratories, Inc. (1978)
	Tetanus and diphtheria toxoids adsorbed (for adult use)	Eli Lilly and Company ¹ Wyeth Laboratories
1955	Poliomyelitis vaccine	Merck Sharp and Dohme* Parke, Davis and Company*
1957	Adenovirus vaccine	Parke, Davis and Company •
1959	Adenovirus and influenza virus vaccines combined aluminum phosphate adsorbed	Parke, Davis and Company*
	Diphtheria, tetanus, toxoids, pertussis, poliomyelitis vaccines adsorbed	Parke, Davis and Company •
	Diphtheria and tetanus toxoids, pertussis vaccine adsorbed, and poliomyelitis vaccine	Parke, Davis and Company (1963)
1960	Poliomyelitis vaccine adsorbed	Parke, Davis and Company •
1961	Poliovirus vaccine live, oral, Type 1	Pfizer, Ltd. •
	Poliovirus vaccine, live, oral, Type 2	Pfizer, Ltd. •

Footnotes appear at end of table

Table 2.3A—Chronological Introduction of Types of Vaccine Products Still Licensed in the United States (continued)

Year	Type of vaccine product	Establishment with oldest product license still in effect ^a
1962	Poliovirus vaccine, live, oral, Type 3	Pfizer, Ltd.*
	Measles virus vaccine live, attenuated	Lederle Laboratories*
	Poliovirus vaccine live, oral, trivalent	Merck Sharp and Dohme*
1967	Measles-smallpox vaccine, live	Lederle Laboratories*
	Mumps virus vaccine	Merck Sharp and Dohme*
1969	Rubella virus vaccine, live	Merck Sharp and Dohme*
1970	Anthrax vaccine adsorbed	Bureau of Laboratories, Michigan Department of Public Health*
	Rubella and mumps virus vaccine, live	Merck Sharp and Dohme*
1971	Measles and rubella virus vaccine, live	Merck Sharp and Dohme*
	Measles, mumps, and rubella virus vaccine, live	Merck Sharp and Dohme*
1973	Measles and mumps virus vaccine, live	Merck Sharp and Dohme*
1974	Meningococcal polysaccharide vaccine, Group C	Merck Sharp and Dohme*
1975	Meningococcal polysaccharide vaccine, Group A	Merck Sharp and Dohme*
	Meningococcal polysaccharide vaccine, Groups A and C combined	Merck Sharp and Dohme*
1977	Pneumococcal vaccine, polyvalent	Merck Sharp and Dohme*

^aDates in parentheses indicate dates of product licensure for vaccine products for which original license holders no longer hold licenses

*Establishment issued original product license.

SOURCE: OTA's interpretation of data provided by the Bureau of Biologics, 1979.

Table 2.3 B—Establishments Holding Original Licenses for Vaccine Products Still Licensed in the United States (1979)

Type and name of establishment	Number of original product licenses
American pharmaceutical companies	
Cutter Laboratories	1
Eli Lilly and Company	4
Lederle Laboratories	7
Merck Sharp and Dohme	14
Parke, Davis and Company	10
Wyeth Laboratories	1
Subtotal	37 (89%)
Foreign-based institutions	
Pfizer, Ltd.	3 (7%)
State governments	
Bureau of Laboratories, Michigan Department of Public Health	1 (2%)
American universities	
University of Illinois	1 (2%)
Total	42 (100%)

SOURCE: OTA's Interpretation of data provided by the Bureau of Biologics 1979