Notes

Chapter 1  Drug Therapy: From “Baby Killers” to Baby Savers, 1906–1933

1 The laws have generated pediatric-related information on more than 400 drugs. Dianne Murphy, MD, “Overview and Impact of the Pediatric Legislation (since 1997),” “Comments on Specific Tasks: Drug Labeling, Tasks 1 and 2,” Meeting 1: Pediatric Studies Conducted under BPCA and PREA, Institute of Medicine, Washington, DC, 17 December 2010; Powerpoint of talk, accessed August 1, 2016, http://www.nationalacademies.org/hmd/Activities/Children/PediatricStudiesBPCAPREA/2010-DEC-17.aspx.


I. Glenn Cohen, “Therapeutic Orphans, Pediatric Victims? The Best Pharmaceuticals for Children Act and Existing Pediatric Human Subject Protection,” *Food and...*


Steven Epstein briefly discusses issues of children’s participation in drug trials as part of his valuable analysis, what he calls the emergence of a “biopolitical paradigm” that influenced clinical practice as well as state policy. Children, like women, minorities, and the elderly, are among the many groups recognized to have special pharmacological needs. Epstein, however, focuses largely on the 1980s and 1990s, when the problem I describe in this book is well entrenched. Moreover, children are not the central focus of his study. Steven Epstein, Inclusion: The Politics of Medical Difference (Chicago: University of Chicago Press, 2007), 61, 116–122.


Glenn Sonnedecker, Kremer and Urdang’s History of Pharmacy, 4th edition (Philadelphia: J. P. Lippincott, 1976), 157, 339–345; Young, Pure Food, 44–59. There were no laws barring the sale or advertising of any drug in the United States in the nineteenth century. In 1879 the first federal bill regulating food and drugs was introduced. This early bill had more to do with food adulteration than with drugs. It did not pass, nor did any of the dozens of similar bills between 1879 and 1906. Mitchell Okun, Fair Play in the Marketplace: The First Battle for Pure Food and Drugs (Dekalb: Northern Illinois University Press, 2006).

For more on the history of Mrs. Winslow’s Soothing Syrup, see Denise M. Kohn, “Laura Jane Curtis Bullard,” Legacy 21 (2004): 74–82. Soothing syrups were among

20 Young, “‘Even to a Suckling Infant,’” 5–32.


These guidelines assured a common nomenclature and chemical composition for all drugs. The USP set standards for strength, quality, and purity for drugs and the National Formulary set standards for “unofficial” drugs such as botanicals, elixers, and excipients. The organizations merged in the 1970s. For a history of the USP and NF, see Lee Anderson and Gregory J. Higby, *The Spirit of Voluntarism: A Legacy of Commitment and Contribution: The United States Pharmacopeia, 1820–1995* (Rockville, MD: United States Pharmacopetal Convention, 1995); Glenn Sonnedecker,

30 Young, “‘Even to a Suckling Infant,’” 5–32.


41 Marks, *The Progress of Experiment*, 75.


Chapter 2  New Drugs, Old Problems in Pediatrics: From Therapeutic Nihilism to the Antibiotic Era, 1933–1945

1 J. P. Crozer Griffith and A. Graeme Mitchell, *The Diseases of Infants and Children* (Philadelphia: W. B. Saunders, 1933), 176; this book is still in print in its 20th

2 Charles A. Janeway to Estes Kefauver, 23 July 1962, Box 62, Folder 13, Helen B. Taussig papers, Alan Mason Chesney Archives of the Johns Hopkins Medical Institutions, Baltimore, Maryland.


6 “Dear Doctor” Cover letter, William N. Bradley and H. Harris Perlman, September 20, 1933, Box 16, Folder 8, PPS records.

7 Pediatric societies around the country quickly gave their full support to the Philadelphia physicians’ proposal; for example, see Minutes of meeting, October 20, 1933, Rochester Pediatric Society Miner Library Archives, Academy of Medicine Collection, University of Rochester, Rochester, New York. See also “Pediatricians Heard from to Date” [undated, appears to be late 1933 or early 1934], Box 16, Folder 8, PPS records.

8 “Resolution Presented to Board of Directors Meeting of the Philadelphia Pediatric Society,” January 17, 1933, Box 16, Folder 8, PPS records.


12 Isaac Abt to H. Harris Perlman, July 27, 1933, Box 16, Folder 8, PPS records.


14 “Report of the Committee on Revision of the Pharmacopeia” as it outlined its work for the coming year. Document undated but included with items from 1936. Committee on Revision of the Pharmacopeia, Committee on Drugs records, American Academy of Pediatrics, Pediatric History Center, Elk Grove Village, Illinois (hereafter cited as COD archives).

15 Folder: “Committee on Drugs: History”: Minutes of the Executive Board of the AAP, June 8, 1938; COD archives. There is nothing in the USP Executive Committee minutes about the AAP request, or any recorded vote on the matter, MSS 149, Box 160, United States Pharmacopeial Convention Archives, Wisconsin Historical Society, Madison, Wisconsin.


For an example of a meningococcal serum reaction, see “Patient Records, 1935–1936,” Series II, Box 19, Case 31671, Sydenham Hospital, Baltimore, Sydenham Hospital Records, 1909–1962, Modern Manuscripts Collection, History of Medicine Division, National Library of Medicine, Bethesda, Maryland (MS C 243) (hereafter cited as Sydenham records). For an example of a case of fatal serum reaction in a pediatric patient elsewhere, see Case 973, Babies Hospital Case Histories, 1932–1955, Archives and Special Collections, Columbia University Medical Center, Columbia University, New York. For a review of clinicians’ concerns about the complexity of drawing blood from, and administering intravenous injections to infants, see Alice Haehnlen, “A Simple Method of Procuring Blood for Diagnosis from Infants,” American Journal of Nursing 21 (August 1921): 786–788.


The treatment protocol is detailed in Memorandum from Dr. Francis F. Schwentker, July 1, 1936, Series IV, “Minutes of staff meetings,” 1935–1937, Box 81, Folder 7, Sydenham records.

For concerns about Sydenham serum relative to Johns Hopkins, see Thomas R. Boggs to Huntingdon Williams, May 15, 1935, Series IV, Box 81, Folder 7; Minutes of Staff Meetings, 1935–1937, Sydenham records. Francis F. Schwentker attended Union College and The Johns Hopkins University School of Medicine, graduating in 1929. After completing a residency at Hopkins in pediatrics, he accepted a position at the Rockefeller Institute. He stayed at Sydenham for three years, leaving in 1938 to go to Romania on behalf of Rockefeller. Francis F. Schwentker (Obituary), Pediatrics 16 (July 1995): 132–134; Park et al., The Harriet Lane Home, 224–238.

33 During the second decade of the twentieth century, for example, whooping cough (pertussis) mortality was three to six times higher in Baltimore’s black infants than in white; Samuel K. Roberts, *Infectious Fear: Politics, Disease and the Health Effects of Segregation* (Chapel Hill: University of North Carolina Press, 2009), 69.
36 Ibid.
39 Musgrave, “Medical Science Conquers a Foe.” The pace of change from serum to serum and sulfa to sulfa only is not clearly documented for the years 1937 to 1940. By 1941, however, the annual report noted, “All cases of meningococcus meningitis received one of the several sulfonamides but anti-meningococcus serum was not used.” City of Baltimore, *One Hundred and Twenty-Seventh Annual Report of the Department of Health* (Baltimore, Health Department, 1941), 121.


Harry Haller, “Sydenham Checks Two Scourges,” Baltimore Sun, August 6, 1939.


Ibid., 891.

“Pneumonia, America’s No. 1 Killer, Declared Conquered,” Los Angeles Times, March 3, 1939.


City of Baltimore, One Hundred and Thirty-Third Annual Report of the Department of Health (Baltimore, Health Department, 1947), 103.

John P. Swann, “The 1941 Sulfathiazole Disaster and the Birth of Good Manufacturing Practices,” Pharmacy in History 41, no. 1 (1999): 16–25. The FDA also sought new ways to protect patients in the aftermath of the 1938 law. For example, it disseminated public policy statements, known as “trade correspondence” because they often rose in response to industry queries. These communiques specified labeling, directions for use, and other rules governing drug sales. Where data were available, pediatric directions for use or warning labels were provided, but this occurred very infrequently. See, for example, pediatric dosing and instructions for chinchona alkaloids (TC-392, August 20, 1942) in Vincent A. Kleinfeld and Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Records 1938–1949 (New York: Commerce Clearing House, 1950), 728.

Harry F. Dowling, Fighting Infection: Conquests of the Twentieth Century (Cambridge, MA: Harvard University Press, 1977), 122; Lesch, The First Miracle Drugs, 216–220; City of Baltimore, One Hundred and Twenty-Seventh Annual Report (Baltimore, Health Department, 1941) 28; City of Baltimore, One Hundred and Twenty-Eighth Annual Report (Baltimore, Health Department, 1942), 30. The Annual Reports show that new sulfa drugs were introduced very quickly: 1936 para-amino-benzene-sulfonamide, 1937 sulfanilamide, 1938 sulfapyridine, 1939 sulfathiazole, 1941 sulfadiazine, 1943 and sulfapyrazine.

Dowling, Fighting Infection, 125. For histories of penicillin, see Robert Bud, Penicillin: Triumph and Tragedy (New York: Oxford University Press, 2007); Scott H.


69 Chester S. Keefer to Wesley W. Spink, July 1, 1942; D. F. Robertson, Associate Medical Director Merck & Co, to Wesley W. Spink, July 10, 1942; Airmail Receipt Merck & Co to Wesley Spink, July 9, 1942, Box 32, Folder, “Penicillin Miscellaneous,” Wesley W. Spink papers, University Archives, University of Minnesota, Minneapolis. For a citation that Spink was the first to use penicillin in an American child, see also Historical Archives Advisory Committee, “Committee Report: American Pediatrics: Milestones at the Millennium,” *Pediatrics* 107 (June 2001): 1482–1491.


71 Adams, *Greatest Good to the Greatest Number*, 31; Johns Hopkins Medical Institutions, Patient A. Medical Record numbers are anonymized to protect patient privacy per Johns Hopkins Hospital Medical Institutions’ Privacy Board requirements.

72 Cone Oral History, AAP Oral History, 42.

73 City of Baltimore, *One Hundred and Twenty-Ninth Annual Report* (Baltimore, Health Department, 1943), 28.


78 Stella Goosstray, “School of Nursing and Nursing Service,” *Annual Report for 1945*, 57, Boston Children’s Hospital Archives, Boston, Massachusetts.

79 City of Baltimore, *One Hundred and Thirtieth Annual Report* (Baltimore, Health Department, 1944), 23.


6 Walton Van Winkle, Robert P. Herwick, Herbert O. Calvery, and Austin Smith, “Laboratory and Clinical Appraisal of New Drugs,” JAMA 126, no. 15 (December 1944): 968–961. Drug companies could also avoid expensive and lengthy testing and trials for new products by marketing them as prescription only, since the 1938 law did not require specific dosing and administration information for drugs prescribed by a physician, who presumably knew treatment standards. Federal Food, Drug, and Cosmetic Act of 1938, Section 502, Pub L. No. 717, 52 STAT. 1040.


8 Tobbell, Pills, Power, and Policy, 7.

9 Executive Board meeting, February 3, 1947, p. 50, Committee on Drugs Records, Pediatric History Center, American Academy of Pediatrics, Elk Grove Village, Illinois (hereafter cited as COD archives).


11 AAP Executive Board meeting, February 3, 1947, pp. 50–51, COD archives.
12 Ibid., p. 53.
13 Ibid., p. 54.
15 AAP Executive Board meeting, February 3, 1947, COD archives.
21 May, 1953 Wide World Photo, Drug Topics Photograph Collection, Folder “Babies,” American Institute of the History of Pharmacy, University of Wisconsin School of Pharmacy, Madison.

26 Finland to Hobby, June 3, 1950; Hobby to Finland, June 5, 1950, Box 19, Folder 24, Finland papers.

27 Hobby to Finland, June 5, 1950, Box 19 Folder 24, Finland papers.

28 Finland to Hobby, June 9, 1950, Box 19, Folder 24, Finland papers.

29 Ray A. Patelski to Finland, September 5, 1950, Box 19, Folder 24, Finland papers.

For information about Finland and relationship with Pfizer, see Podolsky, *Antibiotic Era*, 65–66.


31 March 15, 1955, Memorandum to H. R. Stewart from Robert Bittner, Federal Trade Commission Archives, RG 122, Box 245, National Archives and Record Administration, College Park, MD (hereafter cited as FTC archives, NARA).

32 Undated Memorandum from Howard J. Taylor to Pfizer leadership (among them H. R. Stewart), RG 122, Box 245, FTC archives, NARA.


34 Lederle (pharmaceutical branch of American Cyanamid) District Manager’s Weekly Report, August 19, 1955, RG 122, Box 254, FTC archives, NARA.

35 The Squibb tetracycline also added an antifungal antibiotic because antibiotic treatment sometimes resulted in fungal infections. “Dear Doctor” letter from C. B. Richardson of Squibb, July 6, 1956, Box 254, FTC archives, NARA.


Quote from Leslie A. Falk, [Letter], “Will Penicillin Be Used Indiscriminately?” *JAMA* 127, no. 11 (March 17, 1945): 672; see also Herman Goodman [Letter], “Will Penicillin Be Used Indiscriminately?” 672.


Harry Bakwin, “Common Errors in Pediatric Practice,” *New York State Journal of Medicine* 49 (February 1949): 391–396; quote page 396. John Craig is a Discussant at the end of the article.


Milton Markowitz, AAP Oral History Collection, Interviewed by Howard A. Pearson, July 17, 1988, 20, AAP archives.

Ibid.

Ibid.

Lloyd Miller Notes (undated but included with materials from 1952), MSS 149, MAD 4/27/D1-F7 Box 149, Folder 8, U.S. Pharmacopeial Convention Records, Wisconsin Historical Society, Library-Archives Division, Madison (hereafter cited as USP archives).

John L. Harvey, Associate Commissioner FDA, to Lloyd C. Miller, October 8, 1953, Box 149 Folder 8, USP archives.

William T. Alter to Philip C. Jeans, December 5, 1950, Box 175 Folder 1, USP archives.

55. Other members included Henry L. Barnett of Cornell University; Erling Platou of the University of Minnesota, Alexis F. Hartman of Washington University, and Harry C. Shirkey of the University of Cincinnati. Philip C. Jeans to William T. Salter, March 1, 1951, Box 175, Folder 1, USP archives.

56. Adley B. Nichols to Windsor C. Cutting, January 17, 1952, Box 149, Folder 8, Committee on Posology, USP archives. For uses of calcium chloride in this era, see Katharine Dodd, “Special Reviews: Hypocalcemic States,” *Pediatrics* 2 (December 1948): 737–743.

57. Lloyd C. Miller to Harry Shirkey offering him the position, April 18, 1953; Shirkey acceptance to Miller, April 24, 1953, Box 175, Folder 1, USP archives.

58. The CV Shirkey attached to the letter sent to Miller on April 24, 1953, indicated that he was also an associate professor at Cincinnati College of Pharmacy. Harry C. Shirkey CV, Box 175, Folder 1, USP archives. Shirkey’s mentor Ashley Weeks had been asked by Jeans to join. He delegated the assignment to his mentee Shirkey. Oral History of Harry C. Shirkey by William Gerhardt, 1988, Heritage Series Oral History Collection, Pratt History Library, Children’s Hospital Medical Center, Cincinnati, Ohio.

59. Miller to Shirkey, October 13, 1953, Box 149 Folder 8, USP archives.

60. Ibid.

61. Lloyd Miller’s handwritten notes of a meeting with USP president Windsor Cutting, October 24, 1953, Box 149, Folder 8, USP archives.

62. Ibid.

63. Ibid.

64. Harry C. Shirkey to Windsor C. Cutting, August 31, 1953, Box 149, Folder 8, USP archives.

65. Lloyd C. Miller to Harry Shirkey, October 14, 1953, Box 149, Folder 8, USP archives.


67. Shirkey was interested in body surface area, which he and others thought might be a more precise metric than weight or certainly age. Harry C. Shirkey to Lloyd C. Miller, January 22, 1957, Box 175, Folder 1, USP archives.


69. A. J. Thompson, Manager of Standards and Analytical Research, Merck to Lloyd C. Miller, April 29, 1958, Box 175, Folder 1, USP archives.

70. Shirkey to Miller, June 4, 1958, Box 175, Folder 1, USP archives.

71. Ibid.

72. Shirkey to Miller, June 10, 1958, Box 175, Folder 1, USP archives.


Wyeth Director of Clinical Investigation Edward F. Roberts MD to Horace L. Hodes, July 10, 14, 1952, Box 1, Folder 2, Hodes papers.


82 Undated manuscript (but referencing the year 1952 in the manuscript), “Gonococcal Ophthalmia,” Box 1, Folder 43, Hodes papers.


84 Rothman, Strangers at the Bedside, 62; Susan E. Lederer and Michael A. Grodin, “Historical Overview: Pediatric Experimentation,” in Children as Research Subjects: Science, Ethics, and the Law, ed. Michael A. Grodin and Leonard H. Glantz (New York: Oxford University Press, 1994), 3–29. Moreover, just as in earlier eras, if physicians thought a drug held promise, they often employed it first on their own children—as Harvard pediatrician Thomas Cone did when he fought to get penicillin during World War II for his sick child. These physicians would hardly have done so if they did not believe the potential benefit justified the risk. Thomas E. Cone oral history, interviewed by Howard A. Pearson, July 17, 1996, American Academy of Pediatrics Oral History Collection, Elk Grove Village, IL, quote page 42 (hereafter cited as AAP Oral History Collection). Another prominent researcher in this era who experimented on his own children was Jonas Salk, Charlotte DeCroes Jacobs, Jonas Salk: A Life (Oxford: Oxford University Press, 2015), 220.


86 William A Silverman, MD, interviewed by Lawrence M. Gartner, MD, June 10, 1997, AAP Oral History Collection, 11.

87 Ibid.

88 Ibid.

89 Ibid.

90 Ibid.

91 Ibid., 12.


95 On dosing and digoxin, see Gold to Robert F. Ziegler of the Cardiac Clinic at Harriet Lane Home, Harry Gold, MD (1899–1972), March 10, 1947, Papers, Box 12, Folder 9, Medical Center Archives of New York-Presbyterian/Weill Cornell, New York.

96 Sapin, Donoso, and Blumenthal, “Digoxin Dosage.”


100 Loughlin, Alcindor, and Joseph, “Extended Low Level Dosage.”


102 Quote from Emil J. Freireich Oral History, interviewed by Lesley W. Brunet, July 23, 30, August 13, 2001, History of Cancer Collections, MD Anderson Special Collections, Research Medical Library, University of Texas MD Anderson Cancer Center, Houston. For one cancer hospital’s developing pediatric research program see MD Anderson’s annual *Research Reports*, 1955–1970, located at History of Cancer Collections, MD Anderson Special Collections.

104 Ibid., 190.
105 Ibid., 115–118.
106 Ibid., 26.
107 Ibid., 19–45. For an example of one FDA investigator’s report, see William T. Robinson report from January 19, 1954, about the death of an Ohio infant from chloramphenicol, RG 88, File Number 512.103, Box 2891, FDA archives, NARA.
110 An appalled Mrs. J.N.R. (full name abbreviated for privacy purposes) of Lansing, Michigan, for example, wrote to FDA Commissioner George Larrick in February 1960, providing a list of deceased children in her town that she feared had received the drug for “minor infections,” RG 88, File 512.103 (Chloromycetin) 1960 Box 2891, FDA archives, NARA; for evidence that parental fears concerning chloramphenicol-related aplastic anemia reached policymakers, see *Administered Prices in the Drug Industry (Antibiotics): Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, 86th Congress, 2nd Session* (September 7, 1960), Part 24; Kefauver references, pp. 14044, 14045, concerning letters he received from parents whose children suffered from chloramphenicol-related aplastic anemia.
113 Quote from ibid., 204.
115 For use of chloramphenicol in newborns and young infants in this era and its abrupt cessation at the Harriet Lane Home, see Edwards A. Park Papers, Series: Pediatric Diagnostic Index, 1920s–1950s, [Card division 43351662/51] Folder “Therapy, Chloromycetin,” Alan Mason Chesney Medical Archives of the Johns Hopkins Medical Institutions, Baltimore, Maryland. It is not known whether the deaths in these files were related to the drug, from an underlying infectious disease for which the child was receiving the drug, or for some other reason.
116 Personal Conversation, John Swann PhD, FDA History Office, June 8, 2016.
118 Letter to Maxwell Finland from Parke Davis and Company Research laboratories Anthony Glazko, September 14, 1960, Box 4 Folder 20, Finland papers.
119 Letter from Glazko to Rudi Schmid at Boston City Hospital, July 14, 1959, Box 4, Folder 20, Finland papers.
“Research Activities of the FDA Relating to Child Health,” June 11, 1957; both items at FDA History Office.

Speech given by FDA Commissioner Paul S. Dunbar at Tulane University, February 5, 1958, revealed the limits of the FDA’s authority specific to children. Dunbar emphasizes poison prevention and promoting broad public health measures. *The Child and the Law*, RG 88, Box 125, Acc 622379, FDA archives, NARA.


“Pharmacy,” *Boston Children’s Hospital Annual Report for 1960*, Arthur Thompson, Chief Pharmacist, page 142, Children’s Hospital Medical Center, Boston Children’s Hospital Archives, Boston, Massachusetts.


Thompson, “Pharmacy,” 142.

Ibid., 143.

*Nursing Procedure Manual for 1958–1959*, Box 1, Folder 1, Department of Nursing Archival Collection, Children’s Hospital Medical Center, Boston Children’s Hospital Archives, Boston, Massachusetts.

Harry C. Shirkey to Robert W. Elkas (Assistant to Director of Revision, USP), May 26, 1959, Box 175, Folder 1, USP archives; Shirkey to Lloyd C. Miller, May 25, 1960, Box 175, Folder 1, USP archives.


Ibid., 9.

Ibid., 11.


AAP Executive Board Meeting Minutes, October 14, 1960, COD archives.

Harry Shirkey to Lloyd C. Miller, May 10, 1961, Box 175, Folder 1, USP archives.


Ibid., 21.

Ibid., 22.

Ibid., 21.

“Ibid., 21.

Chapter 4  The Growth and Development of the Therapeutic Orphan, 1961–1979

1  Harry C. Shirkey to Lloyd C. Miller, May 10, 1961, Box 175, Folder 1, U.S. Pharmacopeial (USP) Convention Records, Wisconsin Historical Society, Madison, Wisconsin.


11 Kelsey was born in British Columbia in 1914. She earned a PhD in pharmacology and an MD from the University of Chicago. During World War II she studied antimalarial drugs and observed that quinines crossed the placental barrier and affected fetuses differently from adults. She accepted a job at the FDA when she accompanied her husband, also a pharmacologist, to Washington in 1960 when he was offered a post at the NIH, accessed January 5, 2017, http://www.nlm.nih.gov/changingthefaceofmedicine/physicians/biography_182.html; McFadyen, “Thalidomide in America.”


13 Daniel Carpenter, Reputation and Power: Organizational Image and Regulation at the FDA (Princeton, NJ: Princeton University Press, 2010), 213–226, 240–251. By 1962 thalidomide had been removed from use in Germany because of its link to birth defects, although this had not yet been reported in the American press. Taussig graduated from the Johns Hopkins University Medical School in 1927. In 1930 she was named director of the Harriett Lane Home Cardiac Clinic. By the time of the thalidomide scandal she was internationally renowned for co-developing a surgical treatment for a deadly heart defect, Tetralogy of Fallot, with Alfred Blalock in 1945. For an overview of her German trip, see Helen B. Taussig Oral History, interviewed by Charles A. Janeway, September 15, 1976, History of Medicine Division, National Library of Medicine, Bethesda, Maryland, 39–47 (hereafter cited as Taussig Oral History), 74. For more on Taussig’s life and career, see Ellen S. More, Restoring the Balance: Women Physicians and the Profession of Medicine 1850–1995 (Cambridge, MA: Harvard University Press, 2009), 178–179.


16 “Dear Doctor” template for a letter generated by Taussig and sent to leading pediatricians to build support for pediatric drug-related legislation, June 26, 1962, Box 62, Folder 7, Helen B. Taussig Collection, The Alan Mason Chesney Medical Archives of The Johns Hopkins Medical Institutions, Baltimore, Maryland (hereafter cited as Taussig Collection).

17 Philip S. Barba to Helen B. Taussig, July 18, 1962, Box 62 Folder 7, Taussig Collection. For more on American medicine in the 1950s and early 1960s and the fears of socialized medicine, see Rosemary Stevens, American Medicine and the Public Interest: A History of Specialization (New Haven, CT: Yale University Press, 1971).

Ibid.

Helen B. Taussig, “Dangerous Tranquility: Congenital Malformations,” Science 136 (May 25, 1962): 683; Helen B. Taussig, “Thalidomide Syndrome,” Scientific American 207 (August 1962): 29–33. Boxes 34 and 35 of Taussig’s papers contain material concerning her television appearances. On her efforts to generate media support, see, for example, Taussig to Norman Cousins (editor of Saturday Review), July 18, 1962, Box 62, Folder 13, Taussig Collection. For evidence of her work with Kefauver’s committee, see Taussig Oral History, page 46. For other drug-related political work in this era, see Hubert Humphrey, Subcommittee Chair on Government Operations for the Senate to Helen Taussig, October 3, 1962, Box 62, Folder 8, Taussig Collection. Box 62, Folder 17, holds other letters between Taussig and Humphrey.

Drug Industry Antitrust Act: Hearings before the Antitrust Subcommittee, Taussig testimony, 418.

Ibid., 419.

Ralph Smith Presentation at the National Meeting of the Drug and Allied Products Guild, Inc., at Ellenville, New York, June 14, 1962, quote page 8, FDA History Office, White Oak Campus, Silver Spring, Maryland (hereafter cited as FDA History Office).


For years Kelsey received letters from women, thanking her and confiding in her about drug- and health-related issues. Letters for the years 1963–1967 in Box 1, Folders 2, 4, and 8 The thalidomide controversy and lawsuits would continue for decades. It was ultimately estimated that the drug maimed 20,000 and killed 80,000 fetuses. Although the criminal trials of Chemie-Grunenthal, the German company that created and marketed thalidomide beginning in 1957 under the name Contergan, came to an end in 1970, a large number of documents discovered in 2014 revealed secret meetings in 1969 between the company and the German federal health ministry. These materials reveal behind the scenes deal making that disadvantaged thalidomide-afflicted children and their families. They also document a more fulsome account of high level Nazis who served on the Board. Harold Evans, “Thalidomide: How Men Who Blighted Lives of Thousands Evaded Justice,” accessed November 14, 2014, http://www.theguardian.com/society/2014/nov/14/-sp-thalidomide-pill-how-evaded-justice.


“Memorandum to the Executive Board from the Committee on Drug Dosage and Cooperating Organizations,” October 28, 1962, Committee on Drugs records, Pediatric History Center, American Academy of Pediatrics, Elk Grove Village, Illinois (hereafter cited as COD archives); reprinted in Agency Coordination Study,

28 Ibid., 1706; a sampling of responses to Humphrey’s query letter are included in the transcripts on pages 1708–1726.

29 Ibid., 1729; letter of 3/12/63, Humphrey to Luther Terry.

30 Ibid.


32 \textit{Agency Coordination Study, Part 3}, 783.

33 Ibid., 783.

34 Ibid.

35 Ibid., 783–784.

36 Ibid., 784.

37 Charles D. May testimony, Committee on Government Operations, \textit{Agency Coordination Study: Part 3}, 1031; Charles D. May written comments to Humphrey (undated); reprinted in \textit{Agency Coordination Study, Part 4}, 1708.


39 \textit{Agency Coordination Study, Part 4}, 1322–1356.

40 Ibid., 1355.


42 Ibid., 1354.

43 Ibid.

44 Letter to Humphrey from Stuart M. Sessoms, Deputy Director, NIH, dated February 27, 1963, \textit{Agency Coordination Study, Part 4}, 1703.

45 Letter writer’s name is withheld; letter, March 29, 1963, \textit{Agency Coordination Study: Part 3}, 1242.

46 Ibid.


48 Ibid. Shirkey details his FDA consultations to the FDA in a letter to Robert G. Frazier, Secretary AAP, December 28, 1964, COD archives.

49 Robert G. Frazier, Secretary AAP to Shirkey, November 21, 1963; see also COD meeting minutes October 1963, both in COD archives.


51 Shirkey Oral History. According to pharmacologist and scientist Edward G. Feldmann, the term therapeutic orphan was coined in late 1963 or early 1964.
when Feldmann was Director, Scientific Division, American Pharmaceutical Association and worked closely with Shirkey on the problem of pediatric dosing. The phrase was deliberately designed to be provocative and to capture attention. Personal communication with Edward G. Feldmann by author, February 7, 2011. The first published reference to the therapeutic orphan can be found in Harry C. Shirkey, Preface to Dosage-Posology Handbook: Usual Doses for Infants and Children (Washington, DC: American Pharmaceutical Association, 1965), 6.

52 B. Harvey Minchew, “Pediatric Dosage Labeling,” Memorandum of Meeting, November 9, 1965. TheAMA Council on Drugs enacted a resolution in May 1964 requesting that manufacturers include pediatric dosing information. This resolution is described in Joseph F. Saduski, Jr., MD, to J. F. Palmer, MD, November 2, 1965, both items in Box 11, Folder “Medical Advisory Board Fifth Meeting, FDA Agenda for December 14 and 15, 1965,” Wesley W. Spink papers, University Archives, University of Minnesota, Minneapolis.

53 On Shirkey’s concerns, see COD Minutes, December 2, 1966, COD archives.


55 The monthly COD Minutes document variants of these questions were raised repeatedly between 1964 and the late 1960s; see, for example, Minutes, December 2, 1966, COD archives. On NICHD, see Memorandum, Betty Barton to Donald Harting, July 9, 1965, Record Group 443, Office of the NIH Director, Box 104, National Archives and Records Administration, College Park, Maryland (hereafter cited as NARA)


57 Ibid.

58 Ibid.


60 Ibid.


62 “Statement of Investigator,” FDA Form FD 1573, Box 1, Folder 69, “Lincomycin-Correspondence, Research Material, 1964,” Horace L. Hodes, Papers, Mount Sinai Archives, Gustave L. and Janet W. Levy Library, Icahn School of Medicine at Mount Sinai, New York, New York (hereafter cited as Hodes papers).


Ibid.


A. Ashley Weech to Evan Charney, October 15, 1963, Box 30, Folder 2, Beecher papers.

Ibid.

A. Ashley Weech to Evan Charney, February 10, 1964, Box 30, Folder 2, Beecher papers.

Henry K. Beecher to Evan Charney, June 2, 1966, Box 30, Folder 2, Beecher papers.


Clem O. Miller, Foreword, Conference Coordinator, Coordinator of Scientific Committees, Office of the Commissioner, FDA; *Conference on Pediatric


78 Ibid.
79 Ibid., 80.
80 Ibid.
81 Charles F. Weiss, Conference on Pediatric Pharmacology, 82.
82 Ibid.
84 Mildred Spencer, “Medical Editor for the Buffalo Evening News,” Conference on Pediatric Pharmacology, 105.
87 Ibid., 10.
88 Ibid., 11.
89 Ibid., 33.
90 Ibid., 13.
91 Ibid.
92 Melissa A. Warfield to Herbert L. Ley, Director, Bureau of Medicine, 11 April 1967; Letter O. M. Carroll, FDA Acting Deputy Division of Endocrine & Metabolic Drugs to John J. Jennings, Director of Drug Surveillance, May 9, 1967; B. Harvey Minchew, Acting Deputy Director of Bureau of Medicine to Melissa A. Warfield, 23 June 1967, All RG 88, File Number 500.133 (Dosage and Warning Children and Infants) Box 4233, FDA archives, NARA.
94 Ibid., 8.
95 Ibid., 7.
96 Ibid.
Medicine Activities, Board Meeting, 1969,” Modern Manuscripts Collection, History of Medicine Division, National Library of Medicine, Bethesda, Maryland.

99 Ibid., 6. For more internal discussion of FDA’s perceptions of its limited regulatory authority for pediatric specific issues, see letter, Medical Officer Martha M. Freeman, to John Jennings, Acting Deputy Director, Bureau of Medicine, May 1, 1969, RG 88, File number 500.133 “Dosage and Warning Children and Infants,” Box 4233, FDA archives, NARA.


103 Harry C. Shirkey to Irwin A. Schafer, Associate Professor of Pediatrics, Cleveland Metropolitan General Hospital, June 12, 1969, Box 33, Folder 14, Adriani papers.

104 Ibid.


110 Robert Warren to FDA, January 13, 1971, FDA RG 88 File number 500.133 [Dosage and Warning Children and Infants] Box 4847, FDA archives, NARA.


112 Warren to Winkler, March 10, 1971, ibid.

113 COD Minutes, June 10–11, September 23–24, 1971, COD archives.

115 Drug Research Board, Preliminary Report, Conference on Pediatric Pharmacology, 15, November 8–9, 1971, National Academies Archives Collection, Washington, DC. For skepticism within the AAP about this latest gathering’s ability to address pediatric drug-related issues, see COD Minutes, January 10–12, 1972, COD archives.


117 Charles F. Weiss, “Statement of Purpose,” Pediatrics 49 (March 1972): 452. For data on pediatric expertise at FDA, see Bureau of Drugs Weekly, Special Edition, May 1, 1972, Box 12, Folder 7, Kelsey papers. Weiss had recently left Parke Davis and Company and was now on the faculty at the University of Florida Departments of Pediatrics and Pharmacology.


119 Ibid., 11.

120 Ibid.


123 Ibid., 9581.

124 Ibid.


126 Subcommittee on Monopoly, Competitive Programs in the Drug Industry, 9582.

127 Ibid., 9583.

128 Ibid., 9585

129 Ibid., 9588.

130 Ibid., 9587.

131 For more on children’s rights during this period see Mintz, Huck’s Raft, 323–338; Michael Grossberg, “Liberation and Caretaking: Fighting over Children’s Rights


135 Hawes, Children’s Rights, 120–121.


137 COD, General Guidelines, 18. The FDA reviewed the guidelines and accepted them at the October 24–27, AAP COD meeting 4, COD archives.


142 Ibid.

143 The AAP Committee on Drugs trod lightly on the issue of pregnant women. Although documents such as the group’s 1974 guidelines emphasized the need for testing drugs in pregnant women, pediatricians had little authority in this domain because obstetricians oversaw the care of pregnant women. A new medical specialty of maternal-fetal medicine was emerging during this era, but it was not yet recognized. The AAP Committee on the Fetus and Newborn did raise the issue of pregnant women wherever possible. See, for example, Biomedical Ethics and the
Notes to Pages 91–93

Protection of Human Research Subjects: Hearings before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives, 93rd Congress, 1st Session (September 27, 28, 1973) (Washington, DC: GPO, 1974), 272–275. This was not the first time that a health issue seemingly unrelated to abortion became tangled in its politics. An earlier German measles epidemic had created demand for the procedure in middle-class women infected during pregnancy. Leslie J. Reagan, Dangerous Pregnancies: Mothers, Disabilities, and Abortion in Modern America (Berkeley: University of California Press, 2010).


145 Ibid., 208.

146 Ibid.


149 Yaffe to Chief, Institutional Relations Branch, Division of Research Grants, NIH, November 18, 1974; Appended to COD Minutes October 24–27, 1974, COD archives.

150 Thomas C. Smith, MD, PhD, Director, Clinical Pharmacologist at Parke Davis and Company to Jean Lockhart, MD, AAP, November 25, 1974, Box 3, Folder 4, “American Academy of Pediatrics-Task Force on Pediatric Research Informed Consent and Medical Ethics,” Hodes papers.

151 Ibid.

152 Avrum L. Katcher to Horace L. Hodes, January 13, 1975; letter and statements on the importance of fetal research by physician groups in Box 3, Folder 4, “American Academy of Pediatrics-Task Force,” Hodes papers.

153 The COD’s Sanford L. Cohen testified before the National Commission, December 14, 1975. His testimony is appended to January 12–14, 1975, COD minutes, COD archives.


157 Ibid.

158 COD Minutes, October 22–24, 1975; December 13–15, 1976, COD archives.


163 Ibid.


166 Sumner Yaffe, Correspondence to Steven Sawchuk, MD, Director of Medical Services Johnson and Johnson, August 14, 1975; Johnson and Johnson Institute for Pediatric Service Correspondence “Plan for the Development of Clinical Pharmacology” (undated but attached to the letter from Yaffe to Sawchuck), Box 4, Folder 48, “Johnson and Johnson Institute for Pediatric Service, Correspondence, Board Meeting minutes, 1969–1981,” Hodes papers; Sumner Yaffe interview with author, November 1, 2010.


**Chapter 5** A “Big Business Built for Little Customers”: Candy Aspirin, Children, and Poisoning, 1947–1976


2 Aspirin was created in 1899 by Bayer chemist Felix Hoffmann. Plough did not invent the first flavored aspirin; at least one version entered the market in the early 1930s. Advertised to adults, it made few profits. For histories of aspirin, see Diarmuid Jeffreys, *Aspirin: The Remarkable Story of a Wonder Drug* (New York: Bloomsbury, 2004); Charles C. Mann and Mark L. Plummer, *The Aspirin Wars: Money, Medicine, and 100 Years of Rampant Competition* (Brighton, MA: Harvard Business School Press, 1993); and Jan McTavish, “What’s in a Name? Aspirin and the American Medical Association,” *Bulletin of the History of Medicine* 61 (Fall 1987): 343–366. While these histories provide an excellent historical context for aspirin’s role in twentieth-century American health care and business, the role of children’s aspirin in the development of the American aspirin industry is largely absent.

3 Born in 1891 in Tupelo, Mississippi, Plough dropped out of school in the eighth grade. He began his career as an entrepreneur at age sixteen, when he borrowed money from his father to produce “Plough’s Antiseptic Healing Oil.” Made of camphor, carbolic acid, and cottonseed oil stirred in an old kettle, the teenager went up and down the streets of Memphis in a horsedrawn wagon selling his new product. With aggressive advertising and creative marketing, he soon turned a profit. He


8 See, for example, a comparison of St. Joseph’s ads to others in Parents 24 (January–June 1949).

9 It would not be until 1964 that Ebony magazine could purchase a St. Joseph advertisement featuring an African American mother and child; see Ebony 19 (February 1964): 40. For more on racial integration in advertising, see Jason Chambers, Madison Avenue and the Color Line: African Americans in the Advertising Industry (Philadelphia: University of Pennsylvania Press, 2008), 119–145.

10 For Mrs. Donald Crow’s testimonial, see Parents 29 (November 1954): 19. For white male physician and celebrity endorsement, see Parents 33 (December 1958): 3. For another example of using physicians to sell St. Joseph’s, see “Thousands of Doctors Approve,” New York Times, November 30, 1952.

11 For the little girl putting on evening gown, see Parents 24 (January 1949): 46; the little boy putting on the pants of an adult man is in Parents 24 (February 1949): 59.


One of many discussions on the growing role in aspirin in pediatrics as a result of children’s flavored small dose aspirin was held on October 7, 1955, at the AMA Committee on Toxicology: see AMA Committee on Toxicology, “Minutes,” AMA Committee on Toxicology Records, Box 7, vol. 1, 93, 147–148, Arena papers.


For discussions of the problem regarding the lack of standardized dosing, see the Memorandum from January 1955, Folder, Committee on Accident and Poison Prevention, entitled “Precautions Regarding Salicylates, Including Aspirin”; see also a letter from George Wheatley to AAP Executive Director E. H. Christopherson, February 17, 1955, AAP Folder: Committee on Accident and Poison Prevention Correspondence American Academy of Pediatrics, Pediatric History Center, Elk Grove Village, Illinois (hereafter cited as AAP archives). On the early poison control movement, see also Jay M. Arena Oral History by James Gifford, February 28 and March 14, 1984, Duke University Medical Center Archives, Durham, NC (hereafter cited as Arena Oral History) and Wheatley Oral History. For a more recent history of the poison control movement, see Committee on Poison Prevention and Control, *Forging a Poison Prevention and Control System*, Institute of Medicine of the National Academies (Washington, DC: National Academies Press, 2004): 80–105.

W. H. Moses, Houston Inspection Statement to Chief, New Orleans District, June 14, 1954, entitled “Deaths of Infants Following Ingestion of ‘Baby’ Aspirin”; this and other similar letters and reports are in File No. 500.23, Box 1991, Poison Series, Records of the Food and Drug Administration, Record Group 88, National Archives and Records Administration College Park, College Park, MD (hereafter cited as Poison Series, FDA records); For an early history of poison control from the perspective of the FDA, see Wallace F. Janssen, “Warning: Hazardous to Children,” *FDA Consumer* 7 (March 1973): 16–23.

Ibid.


Ibid.

A. Dale Console at Squibb to George Wheatley, May 5, 1954, File No. 500.23, Box 1991, Poison Series, FDA records. In this folder there is a similar letter from Bayer vice president Harry M. Mauss to George Wheatley, February 24, 1954, stressing the importance of parent education.


of science denial and attempts to change mount a public relations war and shift the issue away from the health risk in question, see also Naomi Oreskes and Erik M. Conway, Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming (New York: Bloomsbury, 2010), and Gary Taubes, The Case Against Sugar (New York: Knopf, 2016).


35 Handwritten notes by Kerlan on January 3, 1955, File No. 500.23, Box 1991; Poison Series, FDA records. On Public Health Service attempts to safeguard poisons in household products, see Jones and Benrub, “Poison Politics.”

36 George Wheatley’s concerns about industry’s willingness to take action on behalf of pediatric aspirin poisoning can be found in the Minutes for the Committee on Accident Prevention in August 1954, American Academy of Pediatrics Archives.

37 “Precautions Regarding Salicylates, Including Aspirin,” January 1955, Folder: Committee on Accident and Poison Prevention; see also letter from Wheatley to Christopherson, February 17, 1955; also [undated] Background Information prepared for “Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children,” File No. 500.23, Box 1991, Poison Series, FDA records.


41 Ibid., 14.


43 Wheatley to Christopherson, February 17, 1955.

44 Bulletin of the Committee on Toxicology, AMA Committee on Toxicology, Discussions re: AMA statement, “Candy Medication and Accidental Poisoning,” vol. 1, quote March 16, 1955, 209–210, Committee on Toxicology Bulletins, Box 7, Arena papers.


48 Arena attended Duke University medical school, interned at the Harriet Lane Home at Johns Hopkins Hospital and then returned to Duke for residency and to spend the rest of his career. Arena’s interest in poison arose during his medical school days at Duke University in the early 1930s. The numbers of children seriously injured from ingesting common household products had made a lasting impression, Arena Oral History, 16; Arena, “Poisoning in Infants and Children”; Jay M. Arena, “The Pediatrician’s Role in the Poison Control Movement and Poison Prevention,” *American Journal of Diseases of Children* 137 (September 1983): 870–873; and Wheatley Oral History. For a more recent history of the poison control movement, see Committee on Poison Prevention and Control, *Forging a Poison Prevention and Control System*, 80–105.

49 Arena Oral History, 16.

50 Ibid., 17.

51 Ibid.


54 For Plough safety cap advertisement, see *Parents* 22 (December 1958): 3.

55 For Bayer ad, see *Parents* 34 (November 1959): 24.

Major Childhood Peril,” *New York Times*, April 5, 1957 and “Children, Curious, Are Easy Poison Victims,” *Los Angeles Times*, January 5, 1959. See also Case Reports from the late 1950s, Box 5, DPCC records.


62 At the time the 1962 Drug Amendments Act was passed, an estimated 100,000 to 300,000 over-the-counter drug products on the market needed to be reviewed for efficacy to meet the new law; aspirin was one of them. For a brief summary of this history, see “Over-the-Counter Acetaminophen-Containing Drug Products in Children Background Package,” Joint Nonprescription Drugs Advisory Committee and Pediatric Advisory Committee Meeting, May 17–18 2011, FDA, accessed April 20, 2016, [http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM255306.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM255306.pdf).


64 (Statement of Representative Leonor K. Sullivan), *Congressional Record*, vol. 111, 1341; Section 14 of the Sullivan bill pertained to aspirin.


67 For Subcommittee discussion, see Subcommittee on Accidental Poisoning Meeting, Minutes for 25 October 1965, Committee on Accident Prevention Archives, AAP archives. Arena’s editorial of support was published under the title “Aspirin Packaging Amendment,” *Clinical Pediatrics* 4 (November 1965): 654.

68 There was also more research on how to treat aspirin poisoning by age. The evolving scientific understanding of the infant kidney in this era, for example, helped explain how and why the metabolic sequelae of aspirin poisoning varied by age and other developmental factors. Because young infants’ kidneys could not metabolize and excrete aspirin as readily, for example, toxicity, in the form of dehydration and...
metabolic acidosis, occurred more rapidly. Older children, on the other hand, were more likely to present with a respiratory alkalosis from too much aspirin. Alan K. Done, “Salicylate Poisoning,” *JAMA* 192, no. 9 (May 1965): 770–772.


Janssen Oral History; a copy of the comic book is filed as an addendum.


Ibid., 431.


Ibid., 33.

Ibid.


Ibid.

Ibid., C. Joseph Stetler, August 15, 1966, 91.

Ibid., 86.


Ibid., 116.

Ibid., Harry B. Solmson, August 29, 1966, 134.

Ibid., 134.

Ibid., Maurice L. Tainter, September 12, 1966, 179.

Ibid., 186.

Ibid., 173.

Ibid.


This plan assuaged Sterling’s Maurice L. Tainter, who restated his call to study poisoned toddler “repeaters.” “Prevention of Accidental Ingestion of Salicylate Products by Children,” FDA Papers (March 1967): 4–8, quote page 5.

Unfortunately for Plough, however, a large percentage of the recorded overdoses had used St. Joseph Aspirin for Children, despite the fact it was already packaged with a safety cap. John J. Crotty, “The Epidemiology of Salicylate Poisoning,” Clinical Toxicology 1, no. 4 (1968): 381–386.


Mrs. C.H. (full name abbreviated for privacy purposes) in Oregon to James Goddard, November 24, 1966. For one mother’s ideas for safety caps, see Mrs. P.M., January (no date) 1967 to FDA, both in Box 3991. Many other letters from parents and other consumers offering support and ideas for safety caps can be found in Box 1991 as well as Boxes 4137, 4244, and 4520 in File # 501 (safety caps), FDA archives.

Harry E. Buttee. Asst to the Director, Bureau of Regulatory Compliance, FDA, March 13, 1968 to Mr. R.S.P, File # 501, Box 4137, FDA archives.

Federal Hazardous Substance Act: Hearings Before the Senate Committee on Commerce (Serial No. 91–35), 91st Congress, 1st Session (October 1, 2, 1969), 1.

Ibid. (Statement of Alan K. Done), 77.

Ibid., 77; Shirkey to Frank E. Moss, Chair Subcommittee for Consumers on September 29, 1969, 265–269.

Ibid., Maurice L. Tainter, 194, 170.

Robert Kostello to Phillip Lee, October 6, 1969, RG 88, File number 500.133, “Dosage and Warning Children and Infants,” Box 4233, FDA archives, NARA.

John M. Gowdy, MD, Acting Deputy Associate Director for Medical Review, Bureau of Medicine, FDA to Robert T. Kostello, November 12, 1969, RG 88, File number 500.133, “Dosage and Warning Children and Infants.”

Ibid.


Chapter 6 Children and Psychopharmacology in Postwar America


7 Ibid., 578, 582, 583.


13 After an internship and psychiatry residency at the University of Chicago and Boston Psychopathic Hospital, she arrived at Johns Hopkins in 1928 as a research associate for Adolf Meyer. In 1930 she accepted a position at Bellevue Hospital’s Child Psychiatric Division. Lauretta Bender, “Childhood Schizophrenia,” *Nervous Child* 1 (Spring 1942): 138–140; Lauretta Bender Curriculum Vitae dated January 22, 1973, Box 18, File 4, Lauretta Bender Papers (accession number #90–012), Brooklyn College Library Archives and Special Collections, Brooklyn, New York.


15 Background Material for Preparatory Committees on Personnel and Treatment, Conference on In-Patient Treatment for Children, June 24, 1956, Box 1, Folder 9, Bender papers. See also Lauretta Bender, “A Longitudinal Study of Schizophrenic Children with Autism,” Hospital and Community Psychiatry 20 (August 1969): 230–237; Archie A. Silver, “Report on Somatic Therapies Prepared for Conference on In-Patient Treatment for Children,” June 25, 1956, Box 1, Folder 5, Bender papers.


17 Background Material for Preparatory Committees, 6.


19 Ibid., 479.


25 Lawrence Galton, “A New Drug Brings Relief for the Tense and Anxious,” Cosmopolitan (August 1955): 82–83, quote page 82. For growing concerns about these and other psychoactive drugs’ addictive potential in the mid-1950s, see Herzberg, Happy Pills in America, 90–93.


28 Ibid., 20.

29 Ibid.

30 The Physician’s Drug Reference does mention Miltown as a therapy for muscle spasm from cerebral palsy and for seizures, conditions that can occur in children, although not exclusively. Nonetheless, the Miltown marketing materials made a case for its pediatric use far beyond its FDA-approved label. Physician’s Desk Reference to Pharmaceutical Specialties and Biologicals, 10th edition (Oradell, NJ: Medical Economics, 1956), 583; Miltown: The Tranquilizer with Muscle Relaxant Action, 19–20.


32 Herzberg, Happy Pills in America, 31. Amphetamines were recommended as appetite suppressants to treat obesity in children, just as they were in adults. Leo Kanner and Leon Eisenberg, “Childhood Problems in Relation to the Family,” Pediatrics 20 (July 1957): 155–164. For an overview of the drugs in the context of childhood obesity, see Laura Dawes, Childhood Obesity in America: Biography of an Epidemic (Cambridge, MA: Harvard University Press, 2014), 100–107.


36 For more on the development of the Psychopharmacology Service Center, see Grob, *The Mad among Us*, 210–215, and Tone, *Age of Anxiety*, 82.


38 Ibid., vii.

39 Ibid., vii.


42 Ibid., 22.

43 Ibid., 31.

44 Lauretta Bender, “Discussion,” in ibid., 35.


46 Ibid.


48 Ibid.

49 Ibid.

50 Ibid.


55 EH, “Drugs for Children.”

56 Ibid.

57 There were eleven other federally funded units at this time. For a description of Fish’s early experiments, see Barbara Fish Oral History by Marcia Meldrum and Beth Bromley, September 11, 2008, 41–42, Center for the Study of the History of Neuropsychopharmacology, History and Special Collections, Louise M. Darling Biomedical Library, UCLA, Los Angeles, California. Fish’s close colleague for much of this work was her first research assistant, Dr. Theodore Shapiro, later a professor of pediatrics and psychiatry at Cornell Medical College. He later reminisced about her work at Bellevue: Theodore Shapiro, “Barbara Fish: The Bellevue Years,” *Journal of Child and Adolescent Psychopharmacology* 15 (November 3, 2005): 344–347.

58 For an examination of medical experimentation with LSD in adults, see Erika Dyck, *Psychedelic Psychiatry: LSD from Clinic to Campus* (Baltimore: The Johns Hopkins University Press, 2008).


60 Ibid., 269.

61 Ibid., 268.

62 Ibid.


64 Ibid., 8.

65 Bender, “Children’s Reactions to Psychotomimetic Drugs,” 270.


67 Bender, “Psychotomimetic Drugs,” 270.

68 *Research Program of the Children’s Unit, Creedmoor State Hospital*, March 15, 1968, page 11, Box 2, File 7, Bender papers.


70 Conners oral history; Leon Eisenberg oral history.

71 Letter dated May 24, 1963, from Leon Eisenberg to Senator Hubert Humphrey; *Interagency Coordination in Drug Research and Regulation: Hearings before the Subcommittee on Reorganization and International Organizations of the Committee on Government Operations, Agency Coordination Study: Review of Cooperation on*

72 Ibid.


74 Ibid., 168.


79 Ibid., 288.


81 Ibid.


83 Ibid., 27.


85 Ibid., 72.

86 Ibid., 58.

87 Ibid., 13.

88 Ibid., 24–25.


90 Ibid., 71.

See, for example, testimony Gallagher invited from a mother, Mrs. Daniel Youngs, who charged that school officials diagnosed her child with minimal brain dysfunction, tried to force him to take medication, and harassed the family when they resisted, 77–86.


Ibid., 371.

Ibid., 372–373.

Ibid., 374.


Smith, *Hyperactive*, 94.


Ibid.; undated letter from Alexander M. Schmidt to Dennis Lehr, 400–408.


Leon Eisenberg to Fred H. Frankel, January 31, 1968, Box 8, Folder 61, Henry K. Beecher papers, 1848–1976, H MS c64, Harvard Medical Library, Francis A. Countway Library of Medicine, Boston, Massachusetts.
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105 Judith L. Rapoport Oral History by David Healy, December 1998, page 6, American College of Neuropsychopharmacology, Center for the Study of the History of Neuropsychopharmacology, History and Special Collections, Louise M. Darling Biomedical Library, UCLA, Los Angeles, California.

106 Ibid., 6.


Chapter 7 Pediatric Drug Development and Policy after 1979


**Notes to Pages 145–147**


5 Meyers, *Orphan Drugs*, 50.


7 Ibid., 19, 20.

8 Ibid., Marion J. Finkel, 29–33.


15 Marlene Haffner, “Issues in Pediatric Indications,” Box 28, Folder 5, Kelsey papers.


20 By now Plough was Schering Plough as a result of the merger of the two companies. On the campaign against the science by industry for a number of conditions, including aspirin and Reye’s syndrome, see David Michaels and Celeste Monforton, “Manufacturing Uncertainty: Contested Science and the Protection of the Public’s Health and Environment,” *American Journal of Public Health* 95, S1 (July 2005): S39–S48. For other examples of science denialism, see Naomi Oreskes and Erik M. Conway, Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming (New York: Bloomsbury, 2010); Allan M. Brandt, The Cigarette Century (New York: Basic Books, 2007); Gerald Markowitz and David Rosner, Lead Wars: The Politics of Science and the Fate of America’s Children (Berkeley: University of California Press, 2013).


25 Ibid.


32 Ibid.


34 Mark A. Riddle, Elizabeth A. Kastelic, and Emily Frosch, “Pediatric Psychopharmacology,” *Journal of Child Psychology and Psychiatry* 42 (January 2001): 73–90.

35 “Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients,” *Federal Register* 63, no. 231 (December 2, 1998): 66632–66672.


37 Ibid.

38 Ibid.


42 I appreciate historian Susan E. Lederer’s suggestion that it was not just the era in which the research was occurring, but the age of the experimenter. Lederer argues that their ethical acumen deepened with age and professional maturity (personal communication, Monday, August 8, 2016). My many conversations with historian Janet Golden also shaped my analysis and thinking about this topic. Silverman spent the latter part of his career critiquing early postwar medical research ethics and drawing attention to both the problems and possibilities raised by new therapeutics. See, for example, William A. Silverman, *Retrolental Fibroplasia: A Modern*

A notable exception to the absence of historical research into nurses and human experimentation is Susan Reverby’s work on Eunice Rivers and her role as nurse in the long running Tuskegee experiment, in which indigent African American men were denied penicillin treatment when it became available. Reverby treats Rivers as a significant historical actor and analyzes her in the context of Tuskegee and Public Health Service physicians. Susan M. Reverby, Examining Tuskegee: The Infamous Syphilis Study and Its Legacy (Chapel Hill: University of North Carolina Press, 2009) and Susan M. Reverby, ed., Tuskegee’s Truth: Rethinking the Tuskegee Syphilis Study (Chapel Hill: University of North Carolina Press, 2000). But because so little other historical research explores the role of nurses, it becomes easier to assume that Rivers was an outlier which may or may not be accurate. On nursing ethical codes, see “A Suggested Code: A Code of Ethics Presented for the Consideration of the American Nurses’ Association,” American Journal of Nursing 26 (August 1926): 599–601. See also Guy Philbin and David M. Keepnews, “Edward L. Bernays and Nursing’s Code of Ethics: An Unexplored History,” Nursing History Review 22 (2014): 144–158.


“Dianne Murphy,” FDA Consumer Update, 1.


Stephen P. Spielberg interview by author, January 18, 2013.