Book Reviews


*Children and Drug Safety* provides a carefully researched history of drug therapeutics and policy for children in the USA across the 20th century. The book starts off with a present issue, foreshadowing its main thesis: according to a 2008 report of the US Institute of Medicine, “50 to 75 percent of medications prescribed for children had not received the full panel of tests for safety and efficacy […] believed necessary to protect children” (p. 2). Connolly situates this lack of “child protection” in a longer history of conflicts among various stakeholders, including pharmaceutical companies, governmental agencies, professional associations, doctors, and parents. Throughout the book, Connolly demonstrates how attempts at regulation failed, be it due to the fight of doctors’ associations for political influence or the profit interests of the industry. The result, Connolly argues, was a “knowledge gap” between pediatric and adult drug data that has left a mark on the field until today.

Connolly’s story is, then, one of the distinctiveness of children as a medical population and an assessment of how this distinctiveness played out in the field of therapeutics. Accordingly, the book not only contributes to a neglected topic in the historical scholarship on American pharmaceuticals, but also touches on important issues related to the history of pediatrics and child psychiatry, including professionalization, parental activism, medical ethics, and changes in medical and scientific practice.

The book is structured both chronologically and thematically. The main narrative line runs as follows: Chapter 1 briefly reviews the history of opium-laced soothing syrup in the early 20th century against the background of the professional development of pediatrics and the “child-saving” movement. Connolly points out that major milestones in federal regulation such as the Federal Food and Drugs Act (1906) and the Harrison Narcotic Act (1914) were partly motivated by a widely perceived need to protect youngsters from dangerous patent medications. However, consumer protection ran against the ideals of free enterprise: manufactures tried to sidestep regulatory efforts and the American Medical Association (AMA) opposed federal intervention when perceived as a threat to private practice, exemplified by its resistance to the reauthorization of the Sheppard-Towner Act in the late 1920s.

Putting the failure of drug regulation in the context of conflicting commercial and professional interests also sets one central theme for chapters 2–4 that focus on regulatory efforts for prescription drugs, notably antibiotics. Connolly shows how the introduction of sulfa drugs and penicillin in the 1930s and 40s dovetailed with signif-
significant changes in the structure of pediatric care: drug therapy became “increasingly central to the therapeutic management of the sick child” and care “more hospital-based than ever before” (34). Yet, initial therapeutic success was clouded by a lack of studies on the metabolism and excretion of drugs in children. The occurrence of severe side effects revealed that traditional, proportion-based dosing metrics were not adequate. When broad-spectrum antibiotics poured into the market in the 1950s, the problem became an urgent one. On the one hand, flavored pediatric formula became a major source of revenue for drug companies. On the other hand, the same companies “were also expected to play a major role in tracking any side effects, adverse reactions, and negative outcomes” (58). The data produced were scarce at best. According to Connolly, repeated efforts at regulation by the FDA, the AMA, the American Academy of Pediatrics and the United States Pharmacopeia failed due to political conflicts between the stakeholders and resistance from the industry.

Chapters 5 and 6 turn to over-the-counter and mood-altering drugs, respectively. At the example of candy aspirin, Connolly explains how the pharmaceutical industry was able to fight safety standards such as warning labels and safety cups for many years, denying scientific data and putting the blame for household poisoning on poor parenting. It required consumer activism in the late 1960s and early 1970s to enact measures in the Poison Control Act (1972). Consumer activism also played a role in the history of pediatric psychopharmacology. In the 1940s and 50s, psychoactive drugs provided child psychiatrists with a professional tool to establish mental health as a domain of medical expertise and stabilize diagnostic categories. At the same time, the broad use of psychoactive drugs gave rise to public criticism, informing congressional hearings in the 1970s.

Somewhat ironically, ensuing patient and human subject protection, such as the National Research Act (1974), considerably complicated the testing of drugs in children. Consequently, the “knowledge gap” persisted.

Only recently has the situation improved, Connolly elaborates in Chapter 7. Various legislative initiatives such as the Orphan Drug Act (1983) and the Best Pharmaceuticals for Children and Pediatric Research Equity Act (2002) have set incentives for companies to update labels and made pediatric data mandatory for new drugs. From this perspective, Children and Drug Safety tells a narrative of slow progress. Yet, Connolly emphasizes that it also evidences that sometimes “laws need to be tailored to [the] unique needs [of children]” (160). Indeed, a virtue of her book lies in its effort at connecting the history of American drug therapeutics to an impressive number of child-related issues. As such, it provides a rich source for further scholarly investigations.

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