



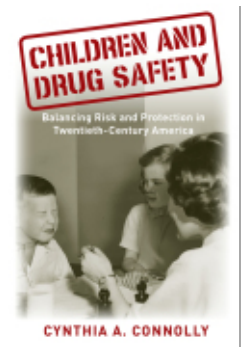
PROJECT MUSE®

---

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

Published by

Connolly, Cynthia A.  
Children and Drug Safety: Balancing Risk and Protection in Twentieth-Century America.  
Rutgers University Press, 2018.  
Project MUSE. <https://muse.jhu.edu/book/58674>.



➔ For additional information about this book  
<https://muse.jhu.edu/book/58674>



This work is licensed under a Creative Commons Attribution 4.0 International License.  
[148.135.83.86] Project MUSE (2025-02-16 13:37 GMT)

## 5

### A “Big Business Built for Little Customers”



#### Candy Aspirin, Children, and Poisoning, 1947–1976

One area of the pediatric drug market that remained robust and immune to the other regulatory changes affecting the prescription drug industry was in over-the-counter drugs.<sup>1</sup> Most had been on the market for decades and brought huge profits to the companies that sold them, none more successful than St. Joseph Aspirin for Children. Its history reveals the advantages and challenges of this pediatric drug market sector. In 1947 the Plough Company, founded by Memphis pharmaceutical entrepreneur Abe Plough several decades earlier, successfully reformulated an old, off-patent medication— aspirin—into a flavored, small-dose chewable tablet designed to appeal to children’s palates.<sup>2</sup> Plough had made his fortune by buying failing proprietary drug companies such as St. Joseph and marketing their products aggressively. Although Plough purchased St. Joseph in 1921, by the 1940s he had yet to see much profit from his investment in the crowded, competitive aspirin market. The explosion of births that began immediately after World War II provided him an opportunity to fill a niche in the market for fever- and pain-reducing drugs. Plough put St. Joseph chemists to work developing a pediatric aspirin formulation attractive to children in both color and taste.<sup>3</sup>

In September 1947, the company released the bright orange-colored St. Joseph Aspirin for Children amid a wave of creative marketing. Advertising

to children and their parents was not new, nor was formulating patent medicines and other substances to appeal to them. Plough was not even the first entrepreneur to create a flavored aspirin; the Food and Drug Administration (FDA) had already flagged an aspirin “lollipop” marketed for use after tonsillectomy to ensure it was not promoted as candy.<sup>4</sup> But Plough was the first to draw direct attention to a reduced-dosage pill tailored especially for the pediatric patient, and it quickly became known as candy aspirin. And he did so at a time when demand for children’s products reached unprecedented levels, the beginning of the baby boom era.

Advertisers increasingly targeted not just parents but children themselves, recognizing their potential to influence family purchases. In line with the trend toward child-sized furniture and foods marketed specifically for children such as sweetened cereals, there was now an aspirin tablet formulated just for them. At the same time, an unprecedented array of toys, games, and books aimed at children entered the market. Health was a visible theme in some of those new products. The Little Golden Book series, for example, included a bestseller that normalized the idea that children regularly took medication. One series character, Nurse Nancy, always had her “handy candy pills” for any



FIGURE 4 Undated fair trade drug price list at drug store of A. W. Boston, Providence, RI. (Credit: “Windows—Babies,” Folder *Drug Topics*, Photograph Collection, American Institute of the History of Pharmacy, University of Wisconsin School of Pharmacy.)

playmate who wanted them. Toy versions of doctor and nurse bags included syringes and vials that could be filled with pretend tablets and liquids, and the companies who produced them benefited from robust sales.<sup>5</sup>

Although Plough used radio and, later, television to sell his products, he relied heavily on newspapers and magazines such as *Life*, the *Saturday Evening Post*, and *Woman's Home Companion* to attract the attention of consumers, particularly mothers.<sup>6</sup> No publication received more of Plough's advertising dollars in the late 1940s and 1950s than the venerable *Parents* magazine. Created in the 1920s by businessman and social worker George Hecht, *Parents* aimed to teach middle-class mothers about all aspects of child rearing. By the late 1940s its advertisers reached nearly one million homes in which at least one child resided.<sup>7</sup> Plough's efforts to attract consumers through *Parents* were remarkable for their size and sophistication. Whereas many ads in the magazine were half- or quarter-page black-and-white sketches, Plough's were full-page color displays with sophisticated illustrations and memorable copy.<sup>8</sup> Like the articles they surrounded, the families and scenarios in the St. Joseph ads presented an idealized, Madison Avenue vision of the American family, replete with overt gendered and classed messages. Mothers in well-appointed living rooms chatted with one another while girls played with dolls and boys with trucks or action toys. The messages were also racially coded: without exception, the children in St. Joseph ads in *Parents* in this era were white.<sup>9</sup>

Occasionally St. Joseph ads carried endorsements by celebrities such as movie and television stars with young children. Testimonials from mothers designed to appear unsolicited framed others. Mrs. Donald Crow from Houston, Texas, for example, appears to have been so pleased with St. Joseph, the ad copy implies, that she sent Plough a picture of herself with her two little boys along with the following note: "My sons hated to take ordinary adult aspirin. There's no fuss now that I give St. Joseph Aspirin for Children. They like its pure orange flavor." Because of physicians' unchallenged status as America's health care authority, many versions of the Plough ads carried a promotion from a physician—always white and male—assuring mothers that there was nothing better they could do for their hurt or febrile child than administer St. Joseph Aspirin for Children.<sup>10</sup>

Although the race, class, and gender messages in these ads were homogeneous, their cultural messages were contradictory. Mothers appeared relaxed, but the copy implied that parenting was stressful and difficult. The ads were designed to tap into mothers' anxieties by persuading them that postwar parenting was much more complex than it had been in the past. As a result, children could face danger if a mother made poor or ill-informed decisions by purchasing a product that had not been scientifically formulated to accommodate their children's physiological and psychological needs. Featured ads for St. Joseph Aspirin for Children throughout the early 1949 *Parents* issues,

for example, emphasized the way the product was tailored for youngsters. “Mother: Here’s the Aspirin Tablet that ‘Fits’ your Child’s Needs” was proclaimed in January that year. The accompanying illustration demonstrated the way a product designed for an adult would not work for a child by showing a little girl trying to put on an evening gown. The next month, a St. Joseph ad showed a little boy putting his legs into pants sized for an adult man.<sup>11</sup> St. Joseph Aspirin for Children’s promotional materials also emphasized the way the flavored, small-dose aspirin tablet reduced medication-related stress. Concern for children’s emotional needs and cognitive development became increasingly important in the early postwar era, so much so that these issues became the central focus of planning for the 1950 White House Conference on Children, as discussed in Chapter 3.<sup>12</sup>

Plough’s new product achieved blockbuster status almost immediately. In 1949, less than two years after the launch of St. Joseph Aspirin for Children, the *Wall Street Journal* reported on the company’s growth and prosperity. This success was attributed, in large part, to children’s aspirin, his “Big Business Built for Little Customers,” as one article in *American Business* lauded.<sup>13</sup> By the early 1950s, surveys of physicians suggested that aspirin was the most common drug used in pediatrics, spurring Bayer and other manufacturers to launch competing versions of reduced-dose, flavored aspirin.<sup>14</sup> Their products, too, sold well and their promotional materials featured the same happy, healthy, white children and relaxed suburban mothers. Plough, though, had a distinct knack for capturing attention, one that helped him break all the company’s sales records.<sup>15</sup> First, he sought to cultivate brand loyalty by reminding mothers that his company’s version was the first—and, as such, the best. He also sought novel ways of capturing potential customers’ attention; for example, he distributed free copies of the company’s St. Joseph 1954 calendar, which featured the Civil Defense Air Raid Instruction Chart do’s and don’t’s for making sure one’s family survived an atomic bomb attack. According to company legend, Plough used another potent marketing strategy. The company hired groups of women posing as mothers to request St. Joseph Aspirin for Children in drug stores in small Southern towns. Once the druggist began stocking it, the women moved on to another area and demanded the product there.<sup>16</sup>

But Plough’s success relied on more than a growing customer base, brilliant advertising, and a product that captured the cultural zeitgeist. St. Joseph Aspirin for Children’s sales also benefited because parents needed no physician prescription to purchase it, in contrast to the broad spectrum antibiotics, steroids, and tranquilizers entering the market at the same time. Although the Federal Trade Commission regulated Plough’s ads in terms of the kinds of claims the company could make, Plough was able to appeal to consumers directly; prescription drug makers could advertise only to physicians.<sup>17</sup> And it was not just parents who were convinced by Plough’s promotional campaigns.

*The Gown Doesn't Fit, Honey...*

—you're not ready for an adult size yet. . . . And mother knows it's the same in aspirin—you're not ready for a 5-grain adult size tablet because it doesn't fit your special dosage needs.

*Mother...*

**HERE'S THE ASPIRIN TABLET THAT "Fits" YOUR CHILD'S NEEDS**

**IT'S ST. JOSEPH ASPIRIN FOR CHILDREN!** Approved by mothers everywhere because it solves child dosage problems and eliminates all guesswork about correct dosage. *Easy To Give* because it's not necessary to cut or break tablets. *Assures Accurate Dosage* because each tablet contains  $1\frac{1}{4}$  grains of aspirin —  $\frac{1}{4}$  the regular 5-grain adult tablet. *Easy To Take* because it's orange flavored and sweetened to a child's taste. Bottle of 50 tablets, 35c.

Be sure to always ask for the original and genuine St. Joseph Aspirin For Children because there is no other product just like it! Buy it now!

**ST. JOSEPH ASPIRIN FOR CHILDREN**

ORANGE FLAVOR SWEETENED

1/4 GRAIN OF PURE ASPIRIN PER TABLET OF THE STRENGTH OF 5 GRAIN ADULT TABLET

PRICE 35c

*Plough, Inc.*  
NEW YORK, N. Y.

**ST. JOSEPH ASPIRIN FOR CHILDREN**

Made by the Makers of St. Joseph Aspirin  
World's Largest Seller at 10c

FIGURE 5 Advertisement, St. Joseph Aspirin for Children, *Parents Magazine*, January 1949.  
(Credit: Courtesy of Foundation Consumer Healthcare.)



*The Trousers Don't Fit, Sonny...*



—you're not ready for an adult size yet. . . . And mother knows it's the same in aspirin—you're not ready for a 5-grain adult size tablet because it doesn't fit your special dosage needs.

*Mother...*  
**HERE'S THE ASPIRIN TABLET THAT "Fits" YOUR CHILD'S NEEDS**

**I**T'S ST. JOSEPH ASPIRIN FOR CHILDREN! Approved by mothers everywhere because it solves child dosage problems and eliminates all guesswork as to the correct dose. *Easy To Give* because it's not necessary to cut or break tablets. *Assures Accurate Dosage* because each tablet is  $\frac{1}{4}$  the regular adult aspirin tablet. *Easy To Take* because they are orange flavored and sweetened. It's the new "Mother-and-Child" favorite. 50 tablets, 35c.

Be sure to always ask for the original and genuine St. Joseph Aspirin For Children because there is no other product just like it! Buy it now!



Made by the Makers of  
St. Joseph Aspirin  
World's Largest Seller at 10c

FIGURE 6 Advertisement, St. Joseph Aspirin for Children, *Parents Magazine*, February 1949.  
(Credit: Courtesy of Foundation Consumer Healthcare.)

Doctors increasingly recommended aspirin for children with minor pain or fever. This was a new trend. Before the advent of St. Joseph Aspirin for Children, for example, the drug was almost never prescribed for children with pneumonia or meningitis at Baltimore's Sydenham Hospital, no matter how high their fever. Until 1949, the last year the institution remained open, ice collars, tepid baths, and other nonpharmacologic treatments remained the primary fever therapeutic. Aspirin was only employed in Sydenham youngsters with rheumatic fever—related inflammation and pain<sup>18</sup> Within a few years of Plough's introduction of St. Joseph Aspirin for Children, the Committee on Toxicology for the American Medical Association (AMA) recognized its escalating popularity and charted the growing use of the "children's size" aspirin for minor pain and fever in the pediatric patient.<sup>19</sup> Even Benjamin Spock was not immune: he did not mention children's aspirin in the 1940s editions of his book, but by the middle of the 1950s he gave it prominent acknowledgment.<sup>20</sup>

### **Candy Aspirin's Unintended Consequence**

By the 1950s, low-dose, flavored aspirin was the number-one drug ingested by children, far outstripping its chief competitor, penicillin.<sup>21</sup> Plough's profits increased by double digits throughout the decade, in some years by as much as 50 percent. Prescription drug manufacturers took notice of Plough's success, competing with one another to create a palatable pediatric formulation for the broad spectrum antibiotics.<sup>22</sup> If the narrative had ended here, in the early 1950s, the candy aspirin story would be a reification of American capitalism's dynamism and societal benefits. But an unintended consequence to candy aspirin's popularity appeared within a few years of its introduction—the incidence of aspirin poisoning in young children increased dramatically. Accidental poisoning in children was, of course, not a new problem. Prescribing manuals as early as the 1880s at the Children's Hospital of Philadelphia, for example, included instructions for purging children of dangerous substances they had ingested. Accidental poisoning in children led to one of the more important additions to FDA authority between the 1914 Harrison Narcotic Act and the 1938 Federal Food, Drug, and Cosmetic Act: the 1927 Federal Caustic Poison Act. This statute mandated that household products include packaging and warning labels, specifically with child protection in mind.<sup>23</sup>

The first suggestion that aspirin poisoning in young children was a significant problem arose in 1952. The American Academy of Pediatrics (AAP) newly created Committee on Accident Prevention began its work by surveying 3,000 pediatricians around the country about mishaps involving young children in the home. The committee's chair, George M. Wheatley, a pediatrician with many years of injury prevention work from his job as vice president of Metropolitan Life Insurance Company, sounded an alarm regarding





FIGURE 7 Beginning in the late 1940s, a bottle of children's aspirin could be found at the bedside of many sick youngsters. Four-year-old boy with mumps, 1968. (Credit: Courtesy of Nicholas Connolly III).

its major finding, the surprisingly high rates of poisoning in young children, especially from aspirin.<sup>24</sup>

Plough's marketing strategy had clearly worked: children loved the taste of St. Joseph Aspirin for Children. But nothing in Plough's advertisements mentioned the importance of keeping it out of the hands of toddlers and preschoolers, and many parents may not have realized that an overdose could

be life-threatening. They were undoubtedly horrified to learn that soon after ingesting a toxic dose of aspirin, children could experience ringing in the ears accompanied by sleepiness, rapid and deep breathing, vomiting, and vision problems. An especially high dose could result in seizures, coma, and even death.<sup>25</sup> Parents themselves even sometimes inadvertently overdosed children. There was no mandate for a standardized children's aspirin preparation. Each company decided how many milligrams of acetylsalicylic acid to put in a tablet. Plough's St. Joseph, for example, sold a 1.25 grain tablet (80 mg), whereas Bayer's was 2.5 grains (160 mg). Parents needed to read the label on each brand carefully. This confusion worried the Committee on Accident Prevention, which publicized the problem. As soon as Wheatley reported that 50 percent of accidents in children were poison-related, interested pediatricians, nurses, and public health officials began tracking all accidental ingestions in children, regionally at first, then nationally. In most instances, aspirin topped the list for medication-related household poisonings.<sup>26</sup>

In 1954, leaders at the FDA began hearing about aspirin poisoning in children from field agents, regional inspectors who served as the agency's eyes and ears on the ground. With regard to drugs, in addition to monitoring factories where they were manufactured, field agents responded to queries and concerns within their geographic area of jurisdiction. In June 1954, field agent W. H. Moses filed a worrisome report with his superiors in Washington, sounding an alarm that pediatric aspirin poisoning was a real problem in his southern region. Not only had his own nephew overdosed, a Texas doctor informed Moses that his hospital "alone had more infant deaths from ingestion of aspirin than the entire city of San Antonio had had from polio over the last two years."<sup>27</sup> By likening aspirin overdose to America's most frightening children's epidemic at that time, the doctor was clearly trying to convince Moses that the issue was a serious one. He pressed Moses regarding the agency's plans to address the problem, since "babies eat it like candy" and "someone should do something to stop these deaths."<sup>28</sup>

Despite the evidence mounting in the news media and professional literature, the aspirin industry, with Plough in the lead, denied that any safety problem with children's aspirin existed. In a 1954 letter to the AAP (with a copy to the FDA), Plough executive vice president Harry B. Solmson challenged the data, claiming that the company had sold thirty-five million packages of St. Joseph Aspirin for Children since 1947 without a problem. "[W]e do not have knowledge of a single instance wherein serious results have accrued," he wrote, "even though we have been made aware of several instances of a young child taking a whole bottle."<sup>29</sup> A piqued Solmson stressed that low dose, flavored aspirin had been created with youngsters' best interests in mind and that he could produce 25,000 letters from consumers thanking the company for

its product. If any action was needed at all, he argued, it was simply parental education.<sup>30</sup>

Others companies that competed in the now crowded children's aspirin market agreed that inadequate parenting was the culprit in aspirin overdoses—if, in fact, any problem existed, which they did not concede. A. Dale Console at Squibb also made sure the FDA received a copy of his letter to the AAP's Wheatley about aspirin safety. In it, he stated that more parents should follow his own example: "I personally make it a practice to place [aspirin] . . . on a high shelf . . . and to twist the screw stopper tight enough that it is virtually impossible for my children to open it."<sup>31</sup> Another aspirin industry executive, Jerome F. Grattan from Carroll Dunham Smith Pharmaceuticals, also wrote to Wheatley and copied the FDA, charging that the "fault lies not with the pharmaceutical manufacturer but with the guardians of the children involved."<sup>32</sup>

Just as the tobacco industry had begun to do by the middle of the 1950s with regard to health risks from cigarettes, aspirin manufacturers shaped the debates concerning aspirin poisoning using similar tactics. Any problems resulting from use of the product was the fault of the individual, not the product. In the case of aspirin, this meant poor parenting. And like the tobacco industry strategy, Solmson denied scientific data and promulgated what he claimed were facts that challenged reports from the AAP, health departments, and FDA with regard to aspirin poisoning and children.<sup>33</sup>

## **The Conference on Accidental Aspirin Poisoning and Its Aftermath**

Growing concerns about candy aspirin poisoning led the FDA to convene a meeting about the problem in February 1955, one of the first times it brought stakeholders together to discuss an issue specific to the pediatric population.<sup>34</sup> The FDA staffers overseeing the gathering, physician and assistant medical director Irvin Kerlan and director of public information Wallace F. Janssen, knew they faced an uphill battle getting industry even to acknowledge aspirin poisoning was a public health problem. Manufacturers' recent letter-writing campaign to the FDA and AAP had made that clear. In his scrawled planning notes for the meeting, Kerlan mused that he hoped to balance what he thought was an ideal solution with what might be "feasible" in terms of manufacturer cooperation. Kerlan was undoubtedly aware that just a few years earlier the Public Health Service had lost its battle to force manufacturers to package household-cleaning products more securely to prevent child access.<sup>35</sup> Wheatley agreed with Kerlan. The AAP Committee on Accident Prevention minutes before the FDA meeting documented his "considerable correspondence"

with manufacturers of “candy-coated aspirin” and his frustration that they were reluctant to admit any problem resulting from the medication.<sup>36</sup>

The FDA, AMA, and AAP leaders who attended the February 1955 conference, accompanied by vocal supporters from the American Public Health Association, hoped to obtain an affirmative response on two major issues from the eleven manufacturers who agreed to attend, Plough among them. They wanted aspirin makers to place a label on aspirin bottles warning parents to make sure the bottles were kept away from young children. They also sought manufacturer agreement for a standard dosage across the industry for what constituted a child-size tablet to minimize consumer confusion.<sup>37</sup>

Aspirin makers arrived at the meeting harboring a very different agenda than the FDA. The drug industry trade journal *F-D-C Reports* had outlined their strategy. They wanted to forestall with their presence “drastic and unrealistic measures”—such as banning flavored aspirin, which had been proposed by some physicians, particularly pediatricians.<sup>38</sup> The aspirin industry got its wish. Despite heavy pressure from FDA staffers and pediatricians, the only concrete plan arising from the conference was a recommendation that industry voluntarily consider different packaging. While there was tentative industry agreement for an aspirin warning label, no timeline for how this might happen was outlined nor any wording specified.<sup>39</sup> With relief, the *F-D-C Drug Letter* reassured its readers the week after the conference that the FDA would “go slow” and that the agency probably lacked the legal authority to mandate a standardized dosage per pill.<sup>40</sup> But through their discussions at the conference, aspirin makers also realized that a voluntary parental education campaign on their part could also work to their advantage: “From a PR [public relations] standpoint, a general program involving all medications could have the result of converting the suggested salicylate warning statement from a potential liability into an industry-wide asset . . . and might forestall any potential govt. or MD program that would overemphasize the ‘poisoning’ aspect of the situation.”<sup>41</sup>

The absence of any immediate and meaningful action from the conference is interesting, given the 1950s rhetoric surrounding children and their protection. Fears that potentially negative messages in comic books and other popular media might lead to juvenile delinquency and social unrest, for example, figured prominently in the national news around the time the aspirin conference occurred. Legislators and others who expressed concern about reports that portrayed American youth as anything less than happy, healthy, and safe saw a threat to the image of the nation’s ideological superiority to the Soviet Union. So it was ironic that Congress convened a subcommittee on juvenile delinquency, spending three years investigating the potential ways popular culture might harm youngsters, yet showed no interest in legislating safety protections for children stemming from aspirin, despite how extensively the new poison control centers, FDA staff, and AAP leadership documented the problem.<sup>42</sup>

The AAP said little publicly about its disappointment with the meeting's outcome. But in private correspondence Wheatley expressed his frustration to the organization's executive secretary, E. H. Christopherson.<sup>43</sup> His letter reveals that the fault lines that appeared at the FDA conference were some of the same ones that had led to the AAP's founding. Some on the AMA Committee on Toxicology—primarily non-pediatricians—agreed with aspirin manufacturers that what was needed was better parenting. Perrin Long, the eminent Johns Hopkins infectious disease specialist and pharmacologist, for example, expressed his opinion in the immediate aftermath of the aspirin meeting that it was overly indulgent postwar child-rearing practices that created the pediatric aspirin poisoning problem. Although clearly exaggerating, he nonetheless expressed nostalgia for an earlier era of parenting in which little thought was given to whether children liked the taste of their medicine: "[F]rom the beginning of this discussion I have been opposed to candy-coated medication. This business about physical and psychic trauma leaves me cold. In a nation of essentially undisciplined children who have been conditioned in this respect by ethnologists, social anthropologists, and doting psychiatrists, the answer is 'Take this cod liver oil, you little brat, or I will beat hell out of you.'"<sup>44</sup> While some pediatricians agreed with Long, most clinicians by the 1950s underpinned their assessments and interventions using developmental psychology. Drawing on this framework, they viewed youngsters' resistance to foul-tasting medications as normative, given that they lacked the cognitive ability and emotional maturity to understand why they were necessary.<sup>45</sup>

Despite Long's opposition to flavored medication, several months after the FDA-sponsored aspirin conference the AMA Committee on Toxicology published a report in *JAMA* acknowledging that, in addition to aspirin, manufacturers of antibiotics, sulfonamides, barbiturates, antihistamines, and vitamins increasingly sought to appeal to children's palates. Because aspirin was the most widely used medication in children, however, available in most homes, its candy formulations caused the highest number of accidental ingestions. The statistics they cited seemed irrefutable. Whereas 20 percent of aspirin fatalities in prewar America occurred in preschool-age children, by 1951, three years after St. Joseph Aspirin for Children became available, this age group represented 80 percent of aspirin deaths. The committee attributed this fivefold increase to candy aspirin. Their review of data from Chicago's poison control center revealed that in seventy-three of the eighty-four recent pediatric aspirin poisoning cases, children's aspirin was the culprit.<sup>46</sup>

Plough's and other manufacturers' chemists had done their work well. Children simply loved its flavor and marketing campaigns that emphasized its similarity to candy. As Chicago physicians Robert B. Mellins, Joseph R. Christian, and Herman N. Bundesen, observing the new phenomenon of



children's aspirin poisoning, commented: "Children who were old enough to verbalize invariably reported that they sought out and ate the 'aspirin' because they liked the taste. Thus, although the poisoning was *accidental*, the ingestion was clearly *intentional*."<sup>47</sup> According to their analysis, the problem was not that some parents did not read the directions on the bottle; rather, youngsters aggressively hunted for it in medicine cabinets or on counters. As a result, an extraordinary amount of parental diligence was necessary to prevent access to the drug by the determined toddler or preschooler.

As the numbers of aspirin-poisoned children continued to grow, one North Carolina pediatrician at Duke Medical Center, Jay M. Arena, decided to take action. By the 1950s, Arena was one of the nation's leading pediatric poison experts, having recently founded the hospital's poison control center. After two children under age five died in one week from an overdose of "candy aspirin," a frustrated Arena picked up the telephone and called Abe Plough himself at the company's Memphis, Tennessee, headquarters.<sup>48</sup> Bluntly describing the deaths to Plough, he informed him that St. Joseph Aspirin for Children was a "fine product, but I think it's a dangerous product. . . . And you have to do something about it."<sup>49</sup>

Plough was initially reluctant, admitting to Arena he was "scared to death" that taking any action would negatively affect sales for his leading product.<sup>50</sup> Arena responded with an appeal to Plough's marketing sensibility, explaining that St. Joseph Aspirin for Children could differentiate itself from competitors by demonstrating a commitment to child well-being. Arena suggested that Plough could even promote its financial investment for a protective barrier that made it difficult for children to open the bottle as proof of the company's largesse.<sup>51</sup> Plough agreed and assigned one of his employees, Ray L. Sperber, the head of marketing, to work with Arena on a prototype for what would become known as a safety cap. The collaboration began with Arena informing Sperber about his most recent study in the Durham, North Carolina, area. His survey of eight local pediatricians indicated that fifty-six children had overdosed on children's aspirin in a six-month period. Arena informed Sperber that the poison rate was likely even higher than his numbers suggested, however, since 35 to 40 percent of Durham's 70,000 residents were African Americans and he had no data about poison rates in this segment of the population.<sup>52</sup>

It is unclear from Arena's letter to Sperber why poison-related information in African Americans was not possible for him to obtain. Perhaps the health department did not track aspirin overdoses in them, making it difficult to access any data. More likely, the eight pediatricians from whom he obtained information did not accept African American children in their practices, the norm in the segregated South. It is also possible that Arena, like many others, considered blacks so different from whites genetically, physiologically, and behaviorally that he believed trying to gather aspirin poisoning information

about black children would complicate his ability to draw conclusions from his sample. Either way, his matter-of-fact comments provide a clear example of how racialized norms influence research questions in ways that appear invisible to those involved. Nothing in Arena's writings or biographical materials suggests that he was any more racist than other Southern physicians of his era.

Sperber funded Arena's work in 1956 and 1957 to study a few potential safety closures in North Carolina children. Arena eventually concluded that one cap seemed to require more cognitive skill and manual dexterity than the others. He recommended that Plough choose his preferred closure device to be mass produced and affixed to its children's aspirin bottles.<sup>53</sup> In the first advertisement for the safety cap-protected St. Joseph Aspirin for Children, in the December 1958 issue of *Parents*, the company featured it prominently.<sup>54</sup> Within a year Bayer was advertising its safety-capped children's aspirin in *Parents*.<sup>55</sup> Despite the advent of the safety cap, however, mortality rates in young children from aspirin poisoning continued to rise. The determined toddler or preschooler with enough time could overcome the barrier. In an effort to educate parents about this fact, the FDA, poison control centers, and pharmacists' associations instituted public health campaigns focused on aspirin poisoning prevention.<sup>56</sup>

Rising concerns about childhood accidents, including poisoning, were featured prominently at the 1960 White House Conference on Children and Youth.<sup>57</sup> The problem of children's aspirin poison even arose during one of Senator Estes Kefauver's unrelated hearings into issues surrounding price fixing in the pharmaceutical industry. Kefauver's committee reviewed a letter from outgoing FDA physician Barbara Moulton in which she opined, "Baby aspirin still is one of the biggest killers in spite of our aspirin warning, and in spite of the new closure. In my opinion, the only solution is to ban candy-flavored aspirin completely."<sup>58</sup> The AAP journal *Pediatrics* now regularly called for packaging changes to children's aspirin or even its removal from the market.<sup>59</sup> But some physicians continued to debate whether aspirin poisoning represented a public health problem or an individual failure. Boston Children's Hospital pediatrician Roger J. Meyer, for example, argued that a large segment of aspirin-poisoned children hailed from families with "working mothers," "broken homes," and other types of "family pathology."<sup>60</sup>

Those who sought legislative action to address aspirin poisoning were hopeful in 1960, when Congress passed the Hazardous Substances Labeling Act. The law authorized the FDA to require warning labels on products considered dangerous to young children. The statute, however, did not include drugs. Policymakers determined that any such authority should come through drug-related, not poison legislation.<sup>61</sup> Although manufacturers had, by now, agreed to standardize the amount of aspirin (81 mg) in one



FIGURE 8 Passaic County Pharmaceutical Association Poison Prevention poster, 1954. (Credit: Located at the National Library of Medicine. Courtesy of the New Jersey Pharmacists Association.)

children's aspirin tablet, they refused to budge on another issue of importance to the AAP, FDA, and poison control centers: limiting the number of pills per bottle. Poison activists believed that keeping the total dosage contained in one bottle to less than the fatal amount for a preschool-aged child saved lives. But in the context of the thalidomide crisis and other concerns about the pharmaceutical industry ultimately addressed by the Kefauver-Harris Amendments of 1962, the regulatory energy surrounding children's aspirin fell by the wayside in the short term.<sup>62</sup>

### **"Politics in the Pantry and in the Bathroom Medicine Cabinet"**

The aspirin issue roared to life again a few years later. First, in 1964, the respected periodical *Consumer Reports* publicized its concern about "candy aspirin" poisoning.<sup>63</sup> The next year Missouri Democratic Representative Leonor K. Sullivan, learning from one of her constituents that a child had died from a children's aspirin overdose, introduced a bill that prohibited its interstate sale. According to Sullivan, mothers and grandmothers from around the country contacted her with "hair-raising" experiences about the safety cap's inability to prevent ingestions.<sup>64</sup> Sullivan's efforts received publicity, putting the issue back in the legislative spotlight. A few weeks after Sullivan's impassioned remarks on the House floor, prominent investigative journalist Jack Anderson validated her concerns in his *Washington Post* column, noting that his two nieces had just nearly died from flavored aspirin overdoses.<sup>65</sup>

Although Sullivan's proposed statute stalled in the House, South Dakota Senator George McGovern soon introduced his own aspirin-related legislation, the Children's Aspirin Amendment of 1965. He had been alerted to the problem of pediatric aspirin ingestion in young children after a neighbor's child, followed quickly by a staffer's toddler, overdosed. McGovern's measure was less restrictive than Sullivan's in that it did not ban flavored aspirin entirely; rather, it limited the number of tablets in a bottle as poison control activists wanted.<sup>66</sup> Although Jay Arena supported McGovern's bill, it failed to garner endorsement from all poison control leaders, including the AAP Subcommittee on Accidental Poisoning. Several subcommittee members wanted a more restrictive bill, while others saw little reason for a legislative battle because they believed the industry was already working on aspirin-poisoning issues voluntarily.<sup>67</sup> As a result of these divisions, an opportunity for partnership between a powerful senator and one of the nation's leading advocacy groups for children's health, the AAP, faded.

By the mid-1960s, in a trend that surely dismayed the aspirin industry, leading pediatricians' aspirin research focused less on its therapeutic uses and more on its poisoning risks in young children.<sup>68</sup> Meanwhile, the evidence of

its dangers to young children accumulated. In 1964, the Division of Vital Statistics of the Public Health Service attributed 125 deaths in children under five years to aspirin or salicylate poisoning. In 1965, the National Clearing House for Poison Control Centers received 34,483 accidental drug ingestion reports by children under five, of which 16,328 (47 percent) involved aspirin or other salicylates. In 1966 poison control centers documented that 88 percent of the nearly 11,000 children under age five treated in an emergency room for aspirin ingestion had overdosed on a flavored formulation.<sup>69</sup> Prominent papers in large cities such as the *Los Angeles Times* increasingly reminded readers of “sugar-coated” aspirin’s risks.<sup>70</sup>

In this context, FDA staffers Kerlan and Janssen moved to enhance the agency’s regulatory control over children’s aspirin.<sup>71</sup> The FDA was still struggling to establish a clear role for itself regarding the broader problems of children and drug safety, specifically as it juggled the controversial issues of proxy consent, discussions regarding the scientific benchmarks for pediatric drug research, and funding studies in children. But Kerlan and Janssen believed that a consumer education campaign focused on poison prevention was not only noncontroversial, it also unquestionably fell within the agency’s purview and provided an opportunity for the FDA to provide leadership for a major child safety-related issue. They convinced the FDA to commission the popular cartoonist Hank Ketcham to create a child safety story line for his “Dennis the Menace” characters. The resulting “Dennis the Menace Takes a Poke at Poison” comic strip soon found its way into doctors’ offices and health departments around the country.<sup>72</sup> But Kerlan and Janssen did not believe voluntary educational campaigns for children regarding aspirin ingestion were enough. As Janssen later recalled, the mortality figures from flavored aspirin provided the major stimulus for agency support for several bills expanding federal control over hazardous substances. A series of hearings regarding the Child Safety Act (soon renamed the Child Protection Act) were scheduled for 1966. Among the many new powers the law, if enacted, would provide to the FDA was statutory authority to regulate all aspects of manufacturing, bottling, and labeling of children’s aspirin.<sup>73</sup>

### **The 1966 Child Protection Act Hearings: In Whose Best Interest?**

Any hope that children’s aspirin makers harbored for avoiding negative publicity from the Child Protection Act hearings was dashed on March 21, 1966. On that day President Lyndon Johnson issued a statement in which he directly addressed the makers of children’s aspirin. Although most of his remarks concerned the benefits of more careful scrutiny of toys and other “children’s articles,” he called specifically for “limit[ing] the amount of children’s aspirin



available in retail packages" and "requir[ing] certain potent drugs attractive to children to have safety closure caps," exactly the type of federal oversight industry had successfully avoided for many years.<sup>74</sup> The president's statements received heavy coverage in the media. The *New York Times*, for example, featured his comments on page 1, accompanied by details regarding the epidemiology of children's aspirin poisoning.<sup>75</sup>

Aspirin makers seemed stunned by the negative attention. On May 18, at the annual meeting of the Proprietary Association, an industry trade group, James F. Hoge warned his colleagues that the enhanced regulatory power the Kefauver-Harris Amendments had given the FDA over prescription drugs might now envelop over-the-counter agents. Hoge conceded that the makers of proprietary drugs needed to accept that they lived in a "revolutionary time," on the "ascending scale of federal supervision" that had resulted in "limitless boundaries of the welfare state."<sup>76</sup> Nonetheless, he called his colleagues to a "rendezvous with destiny" and draw the line at any new restrictions on children's aspirin packaging, labeling, and marketing.<sup>77</sup>

Hoge suspected that the Child Protection Act hearings in the House of Representatives, scheduled for the summer of 1966, spelled trouble for him and his colleagues. And as he feared, the debate surrounding the need for more federal oversight of children's aspirin became the focal point in five days of riveting testimony and interchange that spanned from June to September 1966. The hearing's only agreement regarding aspirin occurred on the first day, when everyone involved—members of Congress, industry representatives, FDA officers, and pediatricians—agreed to act in a way that benefited children.<sup>78</sup> But it was quickly clear that children were valuable and negotiable political property; there was little consensus among stakeholders for what constituted children's best interests and how that should be determined.

One of the first witnesses, the FDA's crusading new commissioner, James L. Goddard, aimed to set the hearings' tone. After summarizing the escalating pediatric morbidity and mortality from aspirin, he intoned that "every three days a child dies from an overdose of children's aspirin."<sup>79</sup> Goddard stressed the importance of making decisions about the drug's packaging based on aspirin poisoning's pediatric epidemiology. He argued stridently that toddlers and preschoolers were best served by mandating safety caps and limiting the number of pills in a single bottle of aspirin to an amount considered unlikely to be fatal for a child three years of age or younger. Although he acknowledged the broad range of potentially toxic household products beyond aspirin, he was adamant that robust data suggested that "the greatest danger [to children in the home] is posed by the flavored children's aspirin."<sup>80</sup> No doubt to provide a memorable accompaniment to his testimony, Goddard made sure his staff supplied the committee with a number of different types of safety caps to practice opening.<sup>81</sup>

Representative Sullivan also testified, imploring her colleagues not to heed the numerous forthcoming witnesses from the aspirin industry. Both she and Goddard made sure legislators heard that young children overdosed on aspirin in a ratio of four to one relative to other medications. They provided clinical case reports of aspirin-poisoned children with gruesome stories of stomach pumping and other treatments. Policymakers received articles drawn from the popular and scientific literature, along with poignant letters from parents beseeching them to make it harder for their children to overdose.<sup>82</sup> Wisconsin Democratic representative Lynn E. Stalbaum summarized supporters' argument, reminding his colleagues of President Johnson's admonishment that "Children must be our first concern."<sup>83</sup> He concluded his testimony by arguing that there were many things parents could not protect their children from in 1960s America, but an aspirin overdose was not one of them: "We are powerless to guard our children against many of the hazards of 20th-century life. However, thousands of young victims of aspirin poisoning would be alive today if the quantity of aspirin in each container did not constitute a lethal dosage, or if drug containers were secured by safety closures."<sup>84</sup>

Lobbyists for aspirin manufacturers and related trade organizations such as the Pharmaceutical Manufacturers Association (PMA), the Proprietary Association, and the glass and packaging manufacturers that would be affected by mandatory safety closures and package size restrictions also testified. C. Joseph Stetler, president of the PMA, put forward the central pillars of the industry's case for why the aspirin component of the Child Protection Act did not serve children, parents, or the American people. First, Stetler implied that it was industry, not children, who needed protection. Aspirin makers needed to be safeguarded from unwarranted governmental intrusion into their practices because the law would grant the FDA "virtually unlimited authority" to mandate safety caps on any product it chose.<sup>85</sup> The pharmaceutical industry should be celebrated, he proclaimed, because the products manufactured by PMA companies "prolong and save lives."<sup>86</sup> In other words, Stetler insinuated that no new regulations were needed because the industry already acted in children's and the nation's best interest without them.

Richard E. Fisher, director of public affairs for the Glass Container Institute, began his testimony by protesting the need for a safety cap mandate, bolstering Stetler's claim that industry already aggressively protected youngsters: "nowhere has . . . [the safety of children] been given greater priority than in our industry."<sup>87</sup> Attempting to sideline the bill's safety cap mandate for all aspirin bottles, he stipulated that further study was necessary. Finally, he lamented that the voluntary public-private partnership that, in his memory, had worked so well as a result of the 1955 FDA-sponsored aspirin conference, could not be employed again.<sup>88</sup> Fisher's recollections of the 1955 meeting, of course,

differed substantially from recollections of the FDA and AAP participants who attended that event. According to Fisher, the aspirin manufacturers came to the meeting gladly and voluntarily and promptly made changes requested by the FDA. Fisher, of course, did not mention that one reason that Child Protection Act supporters felt so strongly about legislating the number of tablets in a bottle of children's aspirin was because, even eleven years after the meeting, not all manufacturers had followed the 1955 total dosage per unit of sale recommendations.

Aspirin makers, led by Plough, the company with the largest market share, testified next. Plough executive vice president Harry B. Solmson emphasized each of Stetler's and Fisher's points, especially the importance of voluntary action on industry's part. Solmson pointed out to the committee his company's beneficence, reminding them that St. Joseph Aspirin for Children, voluntarily and before any other manufacturer, safety cap-protected its product. He declared that Plough wanted to cooperate with the government, but this "highly controversial bill containing broad new regulatory powers"—it gave the FDA the authority to mandate safety caps on all types of aspirin—went too far.<sup>89</sup> He challenged legislators' claim of public support for the Child Protection Act aspirin provisions by countering that he could produce evidence from consumers who liked St. Joseph Aspirin for Children exactly as it was manufactured and labeled. Plough clearly feared that new aspirin-related mandates could set a precedent for other regulations that the company might not be as willing to enact as the safety cap.<sup>90</sup>

Maurice L. Tainter, vice president of Sterling Drug, the maker of Bayer Children's Aspirin, reiterated and extended his colleague's comments. Just as his predecessors had argued in the past, Tainter maintained that even if pediatric aspirin poisoning was a bona fide health issue, the problem lay not with those who manufactured the product, but with parental negligence. He also warned that safety caps and limits on pill bottle size might increase the numbers of small children accidentally overdosing on aspirin because new restrictions could make adults more complacent, leading them to leave the pills where youngsters could access them.<sup>91</sup> Next, he presented a chart entitled "Recorded Ingestions in 2–5 Year Group Where Age and Dosage Are Known," the data in which, he suggested, showed that children needed to ingest much more than Goddard maintained in order to die.<sup>92</sup> Tainter professed that this was because: "aspirin is different from many other drugs or hazardous substances in that it does not damage the vital organs in such a way as to leave significant permanent injury after such overdosage. Recovery from overdosage is therefore usually prompt and complete."<sup>93</sup>

Tainter went further still. How could anyone even know what an overdose was, he charged, since leading pediatric pharmacologist Harry Shirkey suggested that the weight-based dosing rubrics used to determine dosing

guidelines for most pediatric drugs might not be as accurate as using a child's body surface area as a basis for the calculation? With this argument, Tainter was intimating that perhaps all pediatric drug knowledge was predicated on faulty metrics. If so, his tenuous logic reasoned, aspirin was no less safe than any other drug.<sup>94</sup> But Tainter's words undercut the basic principles behind his product. If Sterling was not sure that the 81 milligrams of aspirin in each Bayer's children's pill was appropriate for a toddler, then why did the company so prominently advertise its safety in *Parents*? Finally, Tainter ended his testimony with a truly audacious ploy—blaming not just parents and the “family environment,” but toddlers and preschoolers themselves for the problem of aspirin poisoning. If there was a problem with children's aspirin ingestion, Tainter's interpretation of the scientific literature was that it might be due to “repeaters” with a “psychological urge” to overdose.<sup>95</sup>

The last witness to testify against the legislation was Proprietary Association president James Hoge, who drove home the all the themes expressed by Stetler, Fisher, Solmson, and Tainter. He warned the subcommittee that “under the heart-stirring’ banner of ‘child safety,’” the proposed laws, if enacted, would give “unlimited delegation of authority to the Food and Drug Administration.”<sup>96</sup> Hoge begged Congress to slow down on what he saw as the most important piece of legislation to affect over-the-counter drugs since 1938. He maintained that aspirin companies “don't need to be policed. They are very law-abiding people, and very high minded, and very much interested in the public health.”<sup>97</sup> He ended with his trump card—that the bill was anti-American because instead of “encourag[ing] private initiative and enterprise,” the proposed legislation moved “far beyond child safety, envelope[d] controversial medical opinion, escalate[d] legal liability, and constrict[ed] industrial independence.”<sup>98</sup>

Industry participants had also come armed with their own letters of support from physicians, albeit not the experts in poison control from the American Academy of Pediatrics and the American Public Health Association that the bill's advocates inserted into the congressional record. Virginia pediatrician Archibald R. MacPherson did not support the aspirin component of the Child Protection Act because he agreed with those who attributed children's aspirin poisoning to poor parenting. He informed Congress that aspirin's packaging and labeling “seem adequate to me” and in the event of an accidental ingestion, “the children's parents are the ones at fault.”<sup>99</sup> And manifesting the enduring struggle for power between the AAP and the AMA as the spokesperson for children's health pertaining to pharmaceuticals, AMA executive vice president F.J.F. Blasingame questioned whether a single pediatric aspirin-related death had ever occurred. Blasingame agreed with MacPherson that, if any children had died from aspirin ingestion, it was a problem that could not be solved

by legislation because the phenomenon "must be traced to parental ignorance, carelessness, or indifference."<sup>100</sup>

By the time the aspirin industry's testimony was over, subcommittee members who had previously supported the FDA's position now felt angry and betrayed by the FDA. New York Democratic representative Leo O'Brien declared that Goddard's original testimony had affected him profoundly: "I would like to say that I attended the first hearing on this bill, and we heard the representatives of the Department [FDA], and I think that before we were through, that most of us were close to tears, weeping for the little children who apparently were being killed in vast numbers by consuming those colored aspirin."<sup>101</sup>

Clearly, O'Brien now felt Goddard had manipulated him. Under the "guise of child safety," he suspected that the FDA was trying to increase the agency's power, exactly what Stetler, Solmson, Tainter, and Hoge had asserted.<sup>102</sup> O'Brien demanded to hear from Goddard again, this time "minus the emotional impact," before we "rewrite a very broad segment of the drug laws."<sup>103</sup> In case anyone on the subcommittee still needed convincing, Hoge interjected a final volley, imploring them not to "rewrite the whole food and drug law under the pretense we are protecting children," which would actually permit the "wanton, unbridled delegation of [FDA] authority."<sup>104</sup>

The tone was very different when Goddard returned to the Hill. Industry had successfully shifted the issue from discussing how best to use the epidemiological evidence gathered by pediatricians, health departments, poison control centers, and the FDA to protect young children, to the need to reign in a rogue federal agency. Goddard's detailed, point-by-point rebuttal to the aspirin industry's charges mostly fell on deaf ears. For example, he explained what he and his staff saw as Tainter's flawed interpretations in his "Recorded Ingestions in 2-5 Year Group Where Age and Dosage Are Known" chart.<sup>105</sup> Analyzing the same data, the FDA concluded that more children did not die from aspirin ingestion not because of its wide safety range, but because of prompt clinical intervention in the form of stomach pumping, blood transfusions, and other "heroic therapy."<sup>106</sup> An annoyed Goddard maintained, "The fact that more lives are not lost hardly proves there is no risk."<sup>107</sup> But there was little congressional follow-up to Goddard's rejoinder to industry. Although Congress did pass the Child Protection Act, the proposal to limit the number of tablets in a bottle of aspirin and other aspirin-related mandates such as safety caps were dropped. Policymakers declared that the problems could be addressed with a voluntary FDA-industry conference, exactly what industry representative Richard E. Fisher suggested in his testimony.<sup>108</sup>



## Mandating Safety Barriers: Industry, FDA, Pediatricians, and Congressional Negotiations

The Child Protection Act congressional hearings showed how easily industry had shifted the terrain from protecting children from aspirin poisoning to safeguarding industry from the federal government. But aspirin manufacturers now faced more negative press from consumer advocates. *Consumer Bulletin*, for example, accused manufacturers of trying to hide aspirin's risks to children in the wake of the hearings, warning parents not to be "disarmed by advertising that shrewdly implies that aspirin is harmless."<sup>109</sup> Nonetheless, the mood was celebratory a few weeks later, in early December 1966, at a Proprietary Association meeting. In the past year, Plough and other aspirin makers had fended off the aspirin regulations in the Child Protection Act and embarrassed FDA commissioner Goddard on Capitol Hill. Joseph M. Pisani, Proprietary Association medical director, extolled the way industry had stalled governmental oversight and "placed the matter in proper perspective" for legislators.<sup>110</sup> While his group had agreed to attend the FDA-sponsored aspirin conference scheduled for early 1967, he dryly signaled his tepid support for labels that alerted parents that flavored aspirin posed a significant poisoning risk to young children: "The label I suggest for 'Safety in the Use of Home Medicines' is read: 'Active Ingredients: Common Sense, Integrity, and Alertness. Warning: *Keep yourself within reach of your children.*' Advertising Copy to accompany this label: 'Use this product as directed and you will keep the American home safe!'"<sup>111</sup>

As with the 1955 FDA-sponsored aspirin meeting, the 1967 conference included representatives from groups active in the poison control movement, aspirin manufacturers, and the FDA. Because of its FDA consultative role, the AAP Committee on Drugs played a central role; as COD leader, Harry Shirkey served as chair. For Shirkey, of course, aspirin poisoning in young children constituted just one piece of what he saw as the much broader issue of inadequate attention to pediatric drug dosing, pharmacokinetics, and other safety metrics.<sup>112</sup>

In his opening remarks at the 1967 aspirin conference, FDA commissioner Goddard admonished stakeholders that he would not hesitate to return to Congress if he determined industry was not participating in good faith. He had been assured, he warned aspirin manufacturers, that "if the problems that had arisen at the Child Protection Act hearings regarding whether or not safety caps should be mandatory and limiting the numbers of tablets in a container could not be solved on a voluntary basis, that [Congress] would be willing to entertain legislation at a future date."<sup>113</sup> Perhaps fearing that Goddard would make good on his threat, industry quickly reached consensus

regarding a pills per bottle industry standard for children's aspirin. After Jay Arena entreated companies to sell safety with the same alacrity that they marketed their products, companies agreed to support a national poison education campaign. Finally, the industry also acquiesced to the FDA request to fund a subgroup of conference attendees, the Subcommittee on Safety Closures, to determine an ideal safety device that all manufacturers could agree to adopt.<sup>114</sup>

The Subcommittee on Safety Closures began its work in April 1967 by first compiling all the information members could find about the fifty barrier devices already patented in the United States. The group also designed research tools to assess the benefits of available closure devices. Some of the data they wanted to collect, however, seemed tangential to their task. For example, some subcommittee members thought it important to gather information on the marital status of mothers enrolled in the studies. Because their central aim was to identify a closure device that would allow ready access for adults, but not children, they understandably sought parental data, but the committee recorded no discussions about why they thought marital status might be relevant. Perhaps some members saw it as a proxy for intelligence, social class, or maternal competence. The subcommittee also did not reach consensus regarding whether to include institutionalized children in their data set. It does not appear those harboring worry about their involvement had ethical concerns. Rather, some subcommittee members believed the data would be skewed because because institutionalized youngsters were probably not a representative sample of toddlers and preschoolers in terms of intellectual and motor development.<sup>115</sup>

Aspirin manufacturers used their participation in the aspirin conference and support for the Subcommittee on Safety Closures in their public relations campaigns. Soon after the conference, for example, Wyeth Laboratories issued a press release informing consumers about its "Safer Packaging for Aspirin Aims To Curb Accidental Poisonings."<sup>116</sup> For its part, the FDA had agreed to a demand from industry to work with the Public Health Service to generate better data regarding the brand and type of aspirin on which children overdosed.<sup>117</sup> This time-consuming task, however, offered little new therapeutic knowledge. Given the increase in aspirin poisoning in the pediatric population after the introduction of children's aspirin, it was already clear that taste mattered. And knowing which brand had hurt a child provided no useful therapeutic information, only an advertising weapon manufacturers could use against one another.

While the Subcommittee on Safety Closures sought to learn more about the demographic characteristics of families in their study, there was little mention of race. This omission is curious, given that a 1968 Public Health Service (PHS) epidemiological study on aspirin poisoning found that more white

than black children overdosed on aspirin. No one seemed interesting in following up on this finding. Was this difference because cases of aspirin poisoning in black children went unreported to the National Clearinghouse for Poison Control Centers? Or was it because black families did not purchase children's aspirin, or restricted access better than white families? The study's lead investigator, John J. Crotty, associate director of the Poison Control Branch of the PHS, did not offer a hypothesis.<sup>118</sup>

Between 1967 and 1971, the Subcommittee on Safety Closures met formally on eight occasions. The group oversaw a series of industry-funded studies that enrolled hundreds of young children, mothers, and older people with the goal of identifying a safety cap that prevented children from opening the bottle but made it as easy as possible for adults to do so.<sup>119</sup> At least some Americans followed the effort closely. The FDA received a number of letters from citizens submitting their safety closure suggestions, drawings, and prototypes.<sup>120</sup> One Oregon mother, for example, summarized her ideas based on the unspecified observation and testing she had done with her own children. The return letters from FDA staffers reveal the agency's frustration at its perceived powerlessness. One FDA response explained to its writer that "the bill was not passed"—that is, the section of the Child Protection Act authorizing FDA to mandate safety caps—so "we have no authority" to oversee the Subcommittee on Safety Closure's efforts.<sup>121</sup>

The FDA and members of the Subcommittee on Safety Closure came to Capitol Hill in October 1969 to report their progress during the Senate Commerce Committee hearings for a new bill, the Poison Prevention Packaging Act. If enacted, the statute would empower the FDA to set "standards for packaging designed to prevent young children from obtaining harmful amounts of hazardous substances found around the home."<sup>122</sup> Alan K. Done, a University of Utah medical school professor and pediatric expert in poison control, attempted to explain the scientific issues to impatient senators who wanted the subcommittee to complete its task. The safety cap issue, he stressed, was not one that could just be solved by engineering:

We have been surprised on numerous occasions when we have developed an innovation that we were absolutely certain would be childproof and the children would fool us. We had one cap, for example, which we specifically designed on the basis of previous failures, to get around the effect we thought existed in the earlier closure. It was absolutely foolproof; you could not get it off. Adults couldn't get them off either unless they knew what to do. The children, in their frustration, quickly learned that if they turned the bottle upside down and hit it on the table one time, the cap would crack and they could immediately get it off.<sup>123</sup>

In a number of ways, the pediatric experts who testified at the 1969 hearings rehashed earlier positions. Some, such as Done, while strongly supportive of safety closures, preferred a voluntary effort on the part of manufacturers rather than a legal mandate. For his part, Harry Shirkey hoped to use the aspirin poisoning issue to justify the need for broad new pediatric drug safety measures.<sup>124</sup> And aspirin manufacturers used the same arguments they had honed in the past—challenge the data, emphasize the benefits of voluntarism, slow the process, and blame aspirin poisoning on nonindustry sources. At the 1969 Poison Prevention Act hearings, Sterling vice president Maurice Tainter, for example, was again eager to blame “Mother’s inadequate awareness of safety requirements in the home over which she presides” and “Dennis the Menace” children, “well known to the psychologist, psychiatrist, or pediatrician.”<sup>125</sup>

Beyond aspirin, the issue for many over-the-counter drugs was not the risk of poison, but dosing confusion, just as was occurring with prescription drugs. This was most problematic for very young children under the age of three years. In their case, most proprietary drug labels instructed parents to contact their physician in advance of administration. In fall 1969, one irate pediatrician, Robert T. Kostello of Chico, California, articulated the bind in which this placed him. In a letter to Phillip Lee, assistant secretary for health and scientific affairs at the Department of Health, Education, and Welfare, Kostello complained: “I object to being consulted about medications which I do not prescribe. . . . This statement puts me in the position of endorsing the medication when a patient calls. . . . I have two choices, either to suggest a dosage, or to advise them I do not use this medication. . . . If the schedule of medication is such that the pharmacist or the drug house dispensing the medication does not know the appropriate dosage, why should the private physician be called regarding this?”<sup>126</sup>

Kostello’s letter eventually reached John M. Gowdy at the FDA Bureau of Medicine, who sent a reply that Kostello surely found frustrating because it elided his concern and, indeed, punctuated his point. After quoting the portions of the laws pertinent to nonprescription drugs, Gowdy informed him that drugs safe for adults may have “special toxicity in children” because youngsters “vary in weight and maturity.”<sup>127</sup> He ended the letter by telling Kostello that “you are perfectly right to suggest a more suitable medication if you believe such a measure appropriate.”<sup>128</sup> But Kostello’s concern was that he, as a private practice pediatrician, had no scientific way of making this determination and needed guidance from the manufacturer, government, or some official source.

## Success—The Poison Prevention Packaging Act

The Poison Prevention Packaging Act stakeholders were able to cobble together enough support to pass legislation requiring all potentially toxic household products to carry child safety closures within a specified period of time. Aspirin was the first product covered by the new law, and the packaging needed to go into effect by August 1973.<sup>129</sup> The Poison Prevention Packaging Act was only one of several new child safety laws in which the FDA was involved. A year earlier, in 1969, President Nixon had signed the Child Protection and Toy Safety Act into law. Like the Poison Prevention Packaging Act, an FDA division was charged with overseeing compliance with the law—in this case, the Bureau of Product Safety (BPS). Division staff in the six-member Toy Safety Review Committee traveled to toy fairs to study prototypes for playthings, evaluating fifty kinds of toys a week. In 1971 alone, BPS director Malcolm Jenson noted that the agency removed five hundred toys from the market.<sup>130</sup>

As FDA commissioner Charles Edwards observed, as a result of the Child Protection and Toy Safety Act, the agency faced a dramatically expanded workload because of the “hundreds of thousands of products” for children it now needed to monitor.<sup>131</sup> The FDA annual reports for the early 1970s reveal the increased time and resources devoted to overseeing child safety packaging and potential problems in toys, clothing, furniture, and other children’s products. The Toy Safety Review Committee oversaw the 83,000 toys produced by 1,200 American toy manufacturers. Sixty-seven million children played with these items, resulting in seven hundred thousand injuries every year. The workload and complexity of tracking all children’s products quickly became so overwhelming that in October 1972, President Nixon signed legislation establishing an independent federal agency, the Consumer Product Safety Commission (CPSC), to free the FDA from this responsibility.<sup>132</sup>

Undoubtedly not lost on the agency itself was the fact that, before toys, furniture, and other children’s products moved to the CPSC, the FDA had authority to protect youngsters from the Do-It-Yourself Bomb Kit toy, which it removed from the market in 1968, but no clear ability to oversee prescription drug safety and efficacy in children.<sup>133</sup> Although the 1962 Kefauver-Harris Amendments theoretically provided the FDA statutory oversight of prescription drugs, the agency had not been able to fully execute those powers when it came to children because no one could figure out who should bear the cost burdens for the additional testing necessary for children and the scientific and ethical issues.

By the mid-1970s, aspirin mortality rates in young children had declined significantly. When Richard Simpson, director of the CPSC, testified on Capitol Hill about the new agency’s successes, he proudly highlighted that safety

caps and other poisoning preventive measures had resulted in a "fairly remarkable decline" in aspirin poisoning in young children.<sup>134</sup> Despite reluctance and delay on the part of many in the aspirin industry, the safety cap campaign is remembered today as a "model for accident prevention in children."<sup>135</sup> Aspirin makers, too, learned valuable lessons in terms of how to respond to the threat of new legislation: challenge the problem's existence and the data underpinning the science; deflect blame; and mount a public relations campaign to confuse the public. These tactics would be used again in the 1980s in the face of a new pediatric threat from aspirin.<sup>136</sup>