Effects of Professional and Media Warnings About the Association Between Aspirin Use in Children and Reye's Syndrome

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IN MANY INDUSTRIALIZED NATIONS, THE PROLIFERATION of health technologies has coincided with increased numbers of epidemiological studies on the risk of injury resulting from medical products and services (Nelkin 1989). Every few months, a previously unknown hazard of a commonly used product is reported in the scientific literature or at scientific meetings. Such reports are often followed by waves of media attention on the dangers in question, accompanied by public and scientific debate about the correct interpretation of these risks. As Feinstein and others (Feinstein 1988) have pointed out, all too often faulty studies purporting to show cause-and-effect relationships between common products and severe adverse outcomes gain widespread media attention, further scaring an already suspicious American public. Media reports tend to concentrate on rare but dramatic hazards, and often fail to report more common but serious risks, such as motor vehicle accidents (Singer and Endreny 1987). Some have suggested that this cycle has created a public "epidemic of apprehension"—even about health technology.

On the positive side, the mass media may be a major channel in alerting the public to important and well-documented dangers, such as

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the carcinogenic potential of asbestos in workplaces, schools, and homes, particularly if the scientific and medical literature diffuses more slowly to appropriate decision makers. In these situations, governments and professional health associations are faced with a dilemma—at what point does sufficient evidence exist to justify public warnings about the potential dangers of specific products that also impart significant health benefits?

Beyond this issue lies another fundamental question: under what circumstances can the lay and medical press influence professional and consumer behavior? Technology-related hazards often appear suddenly and under conditions of uncertainty, and such situations do not lend themselves practically or ethically to the methodological demands of experiments. A fair number of studies exist on the modest effects of mass media campaigns targeting well-established risk behaviors such as smoking (Flay 1987) and seat-belt use (Robertson et al. 1974). However, few explorations of media-related changes in health product use appear in the literature. One study used time-series analysis to observe increases in rates of discontinuation of IUDs and birth control pills following increased news coverage about their adverse effects (Jones, Beniger, and Westoff 1980). Similarly, the Kellogg Company's national television advertising campaign on the role of fiber in preventing cancer was associated with an increase in the market share of Kellogg's and other bran cereals (Warner 1987).

Changes in personal habits are of a different character from changes in purchase decisions following warnings about newly discovered hazards of commonly used products. The desired behavior change represents not the establishment or cessation of a habit, but simply substitution of one product for another closely related product. Marginal changes in behavior are likely to be somewhat easier to achieve than the elimination of a strongly established routine, or adoption of a completely new one (Warner 1987).

This article addresses the question of how the media can change consumer behavior vis-à-vis popular health-related products by focusing on the diffusion of risk information about the relationship between use of aspirin and Reye's syndrome, a rare but potentially fatal or severely debilitating illness usually occurring in young children with flu, varicella, or other viruses. First, we will briefly review the epidemiological evidence supporting the aspirin–Reye's syndrome association. Second, we will describe the actions of several public and private organizations and

the key events that promoted or impeded public awareness. Third, we will report on the relationship between, on the one hand, the quantity and timing of medical and lay media attention to this issue, combined with other public education activities, and, on the other hand, decreases in the use of aspirin for children and reductions in disease incidence. Finally, based on previous research in health education, risk perception, and changing professional behavior, we will propose some specific characteristics of risk communication exemplified by the Reye's syndrome case that may facilitate changes in health behaviors through the use of mass communications.

Epidemiological Studies

Reye's syndrome (RS) is a disease of acute encephalopathy, characterized by a constellation of delirium, fever, convulsions, vomiting, disturbed respiratory patterns, stupor, seizures, or coma typically following an earlier viral illness (Trauner 1982, 1984). The syndrome occurs most often in children between the ages of five and fifteen, and its effects are independent of race, ethnicity, and gender (Trauner 1982). Epidemics are often correlated with influenza and varicella outbreaks, as well as other viral conditions. The syndrome was first described by R.D.K. Reye in the early 1960s (Reye, Morgan, and Baral 1963), and a possible association between ingestion of salicylates and subsequent development of RS was first suggested as early as 1962 (Trauner 1984). National surveillance for RS was begun by the Centers for Disease Control (CDC) during the 1973–1974 nationwide outbreak of influenza B. In late 1976, CDC and state health departments intensified surveillance of the syndrome and have continuously maintained surveillance since then. During the first several years of monitoring, from 250 to 550 cases of RS were reported each year to the CDC, with the largest number of cases occurring during years of influenza A activity. Fatality rates reached 40 percent, but have declined to between 20 and 30 percent more recently (Hurwitz 1988).

Between 1980 and 1982, three case-control studies were published that represented the first major investigations in the United States on the link between ingestion of aspirin and subsequent development of Reye's syndrome. A Michigan study indicated that children with RS were more likely to have received aspirin during a viral illness preceding the onset of RS than controls (Waldman et al. 1982). The authors were

educate parents about the association and to suggest alternatives for treatment of fever (Bess, Helms, and Carter 1986). In late 1984, the American Pharmacy Association, a professional organization registering the community of professional pharmacists, launched a voluntary educational campaign about RS. The campaign included distribution of warning posters to 50,000 members through a weekly newsletter.

Government Activities

Publication of the first three studies linking aspirin and RS resulted in public sector activities to assess the evidence and plan future positions. The Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), both within the U.S. Public Health Service, were the primary actors in the federal government (see table 1). The CDC and its staff carried out the most rigorous epidemiological studies, and also communicated and interpreted study findings for the media and public. The FDA was responsible for ensuring that any important information on risks of aspirin would be communicated both to consumers and to health professionals through public statements, information campaigns, and aspirin warning labels. However, the agency faced two competing pressures: one from the Reagan administration and its Office of Management and Budget, which was attempting to reduce regulatory oversight of private industry; and the other, from Congress and citizen groups, which were demanding government-required warnings about suspected risks as expeditiously as possible.

The aspirin–RS link was not unknown to the FDA at the time the three state studies were published. As early as 1976, the FDA reported indications of a possible association (FDA 1976). It was not until 1982, however, that the agency took an active role in the controversy. In early 1982, an FDA working group conducted a direct audit of the raw data of several state health department studies, and co-sponsored a workshop to discuss the issue with the CDC and the National Institute of Allergy and Infectious Diseases. At the completion of the meeting, a majority of the scientists concluded that the evidence suggesting an association was sufficiently strong to warrant warning health professionals and parents. The pressure on the FDA began to mount in many quarters.

By late March of 1982, the U.S. House of Representatives Subcommittee on Oversight and Investigations had conducted a preliminary

investigation of FDA actions. John Dingell, chairman of the subcommittee, was particularly critical of the FDA's failure to comply with CDC recommendations. Richard Schweiker, secretary of the Department of Health and Human Services (DHHS), announced a directive to the FDA in June 1982 to undertake an educational campaign aimed at health professionals and parents, and a requirement that aspirin labeling be changed to advise against its use in children with influenza or chicken pox. The August *FDA Drug Bulletin* included this information, and served as a further warning to health professionals (FDA 1982). The FDA plan also included broadcasting a series of radio public service announcements (PSAs) and sending brochures to 150,000 pharmacists and 100,000 physicians. However, Secretary Schweiker stopped the proposed rule making for aspirin labeling in the fall of 1982. Several factors probably accounted for this decision. First, on November 9, the American Academy of Pediatrics advised DHHS that labeling of aspirin should be delayed until evidence of the association was more conclusive. Second, based on notes obtained during congressional hearings, the chairman of the House Committee on Natural Resources, Agriculture Research and the Environment also implied that DHHS was acting too quickly. So, on November 18, DHHS announced that new studies were necessary to solve the dispute, and formed a task force to examine the evidence further (*Weekly Pharmacy Reports* 1982a).

The public information campaign, however, did get under way in late 1982, when the surgeon general issued a newspaper column on the association to 8,000 news outlets. In addition, 673,000 copies of an FDA question-and-answer brochure were distributed to pharmacies and primary care physicians. The assistant secretary for health also sent letters to physicians enclosing a brochure on RS (U.S. Department of Health and Human Services 1982; *Weekly Pharmacy Reports* 1982b).

Other potentially more powerful components of the education campaign did not begin smoothly. In the fall of 1983, for example, about half a million FDA-produced pamphlets warning parents of the association were to have been distributed to 4,200 supermarkets but distribution was banned by the secretary of Health and Human Services and the pamphlets remained in a warehouse, largely because of strong lobbying and threatened lawsuits by an aspirin-industry-financed organization of pediatricians, the Committee on the Care of Children (CCC), which was created to counteract the warning campaign. An October 1983 letter from the CCC's attorney outlined the industry's charge that the super-

TABLE 1
Timeline of Major Events and Educational Activities

Year	Government agencies	Warning labels	Industry	Health Research Group
1980	CDC recommends in *MMWR* that caution be used when administering salicylates to treat viral illnesses in children	–	–	–
1981	–	–	–	–
1982	CDC committee finds "high probability" that aspirin contributes to causation of RS; recommends that aspirin not be prescribed for children with chicken pox or influenza Surgeon general column on association to 8,000 newspapers; Q&A brochures distributed to pharmacies and primary care physicians	–	Schering-Plough sends letters to pediatricians stating that recent reports and news stories on relationship between aspirin and RS are "misleading and unjustified"	HRG sues FDA to require warnings on aspirin products
1983	FDA sends TV PSAs to 800 TV stations[a]; newspaper column to 1,500 newspapers	–	CCC press release to news outlets: "Doctors Counter FDA Campaign—Equal Time Request Threatened"	HRG news release: "Government Undercuts Efforts to Warn Parents about RS...."

1984	–	–	CCC television and radio PSA stating that "no medication has been proven to cause Reye's...." American Pharmacy Association warning poster sent to 50,000 members	Letter from HRS to news assignment editors of 1,000 TV stations urging them not to broadcast industry (CCC) PSA
1985	DHHS secretary sends letters on CDC pilot study to pediatricians, family physicians, newspapers, and broadcast outlets	DHHS secretary calls for voluntary labeling by aspirin manufacturers	Aspirin Foundation of America starts voluntary "RS precautionary program," including PSAs, store posters, and signs distributed by sales reps	–
1986	–	Warning labels required on all aspirin products	–	–
1987	–	–	–	–
1988	–	RS warning made permanent, and new requirement that manufacturers place an "attention-getting" statement on the "principal display panel" of packaging to refer to the new warning	–	–

[a] PSAs revised and sent again in subsequent years.

market pamphlet was misleading in implicating aspirin and salicylates as causes of RS, and specifically called for a halt to the publicity campaign and recalls of distributed materials (Chayet 1983). Distribution of a 30-second radio announcement to 5,000 radio stations was also canceled. Television PSAs, however, had already been sent to approximately 800 commercial television stations in the fall of 1983. During this time, a newspaper column prepared by the FDA was distributed to approximately 1,500 newspapers, as well as a new 60-second PSA to 200 television stations. The information in the approved materials was not fundamentally different from previous FDA messages and thus was not affected by the CCC's actions.

The publication of the 1984 PHS pilot study prompted additional waves of FDA and DHHS activity. The Institute of Medicine had already reviewed the data and concluded that they revealed a strong association between RS and the use of aspirin (Institute of Medicine 1983). New DHHS secretary, Margaret Heckler, stated that the study was "not completely conclusive – but its findings do show an association between the use of aspirin and the onset of RS in children and teenagers" with flu and chicken pox. Subsequently, Heckler arranged for letters on the pilot study to be sent to pediatricians, family physicians, newspapers, and broadcast outlets. In addition, in early 1985, she called for voluntary labeling of aspirin products by the Aspirin Foundation of America. She requested that manufacturers remove any labels recommending aspirin for flu or chicken pox in children, and that all aspirin labels contain information on the possible association between aspirin and RS, and a recommendation that aspirin not be used in these circumstances without consulting a physician.

The extent of voluntary compliance by the aspirin industry was controversial. In November 1985, partly because of the pressure from public interest organizations and several U.S. senators, and a realization that the voluntary program was not sufficient, a regulation was approved by Heckler that would require labeling on all salicylate-containing over-the-counter (OTC) medications beginning in June 1986. The warning label required the following statement: "Warning: Children and teenagers should not use this medication for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness" (*Weekly Pharmacy Reports* 1985). This warning was required to precede any additional warning that may appear. The FDA public information campaign continued, with a focus on parents of older children

and teenagers who were likely to be self-medicating (FDA 1985). The campaign included posters for physicians' offices, store posters, PSAs for radio and TV, and new brochures and letters for the public and health professionals.

In June 1988, the FDA requirement for RS warning was made permanent, and a rule was passed requiring that manufacturers place "attention-getting statements on the principal display panel" of packaging to notify consumers about the new warning (*Weekly Pharmacy Reports* 1988).

Consumer Advocacy Organizations

Several private organizations with an active interest in pharmaceutical regulation quickly became embroiled in the ten-year debate and evolution of policies. One of the most active and litigious organizations was the Health Research Group (HRG), led by Dr. Sidney Wolfe. In early 1982, the organization, which has frequently intervened in congressional and agency rule making concerning safety and efficacy of pharmaceuticals, petitioned the FDA to require warning labels on aspirin products. They also publicized the FDA's delay of a major public health campaign about RS, charging that the aspirin industry attempted to stop the government from issuing warnings. In addition, the organization asked the House Committee on Energy and Commerce to investigate FDA delays.

In May 1982, the HRG and the American Public Health Association sued the FDA in Federal District Court in Washington, DC, asking for a requirement that manufacturers place warnings on aspirin products. However, the suit was dismissed in March 1983, when the court ruled that the FDA had not unreasonably delayed rule making on this issue, and that while it was considering such regulations, it had begun an educational campaign to warn the public about potential risks. The court observed, however, that plaintiffs made a strong case that the proposed labeling should be expedited, and left open the possibility for refiling the case if it disagreed with the agency's final decision. In late 1983, HRG sent out a number of news releases charging that the government continued to undercut efforts to warn parents about the aspirin–RS link. It also decried the administration's banning of educational materials (PC/HRG 1983).

In late 1984, the HRG sent a letter to over 1,000 television stations and several hundred radio stations concerning a PSA by the CCC. In it, they quoted the assistant secretary for health's conclusion: "The CCC's messages are misleading . . . and fly in the face of scientific evidence." The letter further urged the broadcasters to report the government's message as often as possible, and not to broadcast the message from the drug industry group (PC/HRG 1984).

On January 9, 1985, the HRG asked the FDA commissioner, Frank Young, to promulgate a regulation requiring all aspirin products to carry a prominent warning label explicitly stating that aspirin should not be used to treat chicken pox or flu symptoms in anyone 19 years or younger (PC/HRG 1985a). Later that month, the HRG petitioned the Federal Trade Commission to require aspirin manufacturers to warn patients about the strong aspirin–RS association (PC/HRG 1985b). In March 1985, the group testified before the House committee on a bill (HR 1381) requiring warning labels, advertisements, and store signs concerning aspirin and RS. Wolfe stated that the voluntary labeling program was a "cruel disaster" based on phone surveys of 53 drug stores in 31 states, and gave examples of aspirin products found in drug stores with labels recommending their use for treatment of flu. They found that none of the surveyed stores had aspirin products with warning labels. In addition, only 17 of the 53 stores had posters, many of which were produced by the American Pharmaceutical Association (Wolfe 1985).

Aspirin Industry Campaigns

Pharmaceutical companies with large shares of the aspirin market played a major role in helping to shape the public debate about the aspirin–RS controversy. Aspirin industry representatives met many times with the FDA, and submitted several analyses to federal officials involved in the labeling and dissemination process. Their earliest efforts were to critically evaluate the case-control studies, and to publish reports questioning their conclusiveness. In March 1982, Plough, Inc. sent letters to pediatricians questioning the validity of recent reports and news stories linking aspirin to RS and recommending continued prescribing of aspirin for the reduction of fever in children (PC/HRG 1982). Other industry-sponsored reports were published as articles or letters in medical journals. For example, the June 1982 issue of *Pediatrics* contained an industry-

sponsored report suggesting that early symptoms of RS preceded and precipitated increased aspirin use in children later diagnosed with RS (Wilson and Brown 1982).

In November 1982, the CCC filed suit in federal district court in Boston seeking a temporary restraining order to prevent the FDA from implementing its public information campaign. Later that month, the district court in Boston denied the petition for a restraining order, and in March 1983, the CCC withdrew its lawsuit. Later that year, the CCC submitted a citizens' petition to the FDA requesting it to issue regulations governing publicity, and asserting that the public education campaign on RS and aspirin was inappropriate. A representative of the CCC met with Assistant Secretary for Health Edward Brandt in an attempt to stave off the publicity campaign. In a letter soon after the meeting, he stated:

> We believe that the massive Government publicity campaign is based on nothing more than sheer speculation and the inability to admit previous error. We believe that the publicity has caused and will continue to cause needless panic, loss of confidence of patients in their physicians, delayed diagnosis of RS, and additional fatal overdose problems related to other medications.
>
> We ask that the present publicity campaign be halted and that materials which have already been distributed be recalled because of the hazard to the public. Instead, we believe that a public service announcement which calls attention to the need for early diagnosis of Reye Syndrome together with the caution relative to the use of all antipyretic medication would be most appropriate. (Chayet 1983)

In October 1983, the CCC sent letters to all commercial television stations, claiming that equal time and the fairness doctrines would apply if PHS ads about RS were run. The organization also sent letters to supermarkets who were to receive the new question-and-answer brochures, advising them that displaying the brochure would be a violation of FDA labeling requirements. The organization also sent a press release entitled "Doctors Counter FDA Campaign–Equal Time Request Threatened," which claimed that most scientific experts agreed that early studies were seriously flawed, and that according to their legal counsel, the FDA was providing misleading and deceptive information. Other industry representatives claimed that the public education program would contain information on the aspirin–RS association, and would thus bias the case-control study designed by the PHS.

Finally, in October 1984, the CCC released a public service announcement to television and radio stations outlining its alternative position in the controversy: "Stay tuned for a medical bulletin on RS. . . . We do know that no medication has been proven to cause Reye's . . . if you would like further information, contact the CCC. . . ." The announcement was made by a physician, who stated that he was a member of a group of 1,200 pediatricians from across the country. This was the same PSA that was denounced by the Health Research Group and the Department of Health and Human Services.

Industry representatives also attempted to obtain prepublication raw data from the CDC pilot study for the stated purposes of determining the validity of study conclusions and defending itself against lawsuits brought by parents of alleged RS victims (Kolata 1986a). After the pilot data (corroborating the early findings of an aspirin–RS link) were submitted to the prestigious *New England Journal of Medicine* for possible publication, the Plough, Inc. director of clinical affairs wrote the journal's editor, Dr. Arnold Relman, calling for a more complete and objective "review of all scientific data underlying this Pilot Study which we believe may be seriously flawed" (Vastagh 1985). The letter described a number of potential biases in the study and requested that they be considered "so that a balanced presentation of this subject matter is available through the *New England Journal of Medicine*" (4). Eventually, in 1986, Plough, Inc. obtained a subpoena allowing its scientists to examine raw data from the government-sponsored study provided that the identities of study participants be excluded (Kolata 1986b).

In January 1985, after DHHS secretary Heckler's call for voluntary labeling of aspirin-containing products, the policy of the aspirin industry began to change gradually. The first to respond was Schering-Plough, Inc. Members of the Aspirin Foundation followed (Sterling, Bristol-Meyers, Miles, Burroughs-Wellcome, Merrill-Dow, and Proctor & Gamble). The factors responsible for these changes in industry policy are not fully understood. The credibility bestowed on the claims of warning proponents resulting from the publication of the pilot study probably accounted for some of the softening in the industry's position. A *Boston Globe* interview with Dr. Joseph White, the president of the Aspirin Foundation, reported his statement that although the government had not yet proven an association between aspirin and RS, the foundation was agreeing to voluntary labeling "to protect those at risk, create some peace and quiet and get some people off the backs of the industry" (Robinson 1985). The programs, negotiated in meetings with the FDA,

included television public service announcements, store campaigns with posters and signs distributed by manufacturers' representatives, and label changes. Some large retailers also planned their own public education activities, including posters and signs in the nonprescription drug sections of pharmacies and food stores.

In 1985, more than 800,000 warning posters were distributed, and radio and TV PSAs were prepared under the auspices of the Aspirin Foundation. In October, the FDA announced that the voluntary relabeling and educational effort was working well, and that 68 percent of children's aspirin on store shelves by the first week of November had the new labeling (*Weekly Pharmacy Reports* 1985). Drugstore marketing services also contained information on the warning poster and a letter from the FDA commissioner urging cooperation with the voluntary program. Although not all manufacturers were equally active in promoting the educational messages, clearly there had been a softening of the aspirin industry's position following the pilot study. This shift in attitude continued and was reinforced by the publication of the final CDC study in 1987 (Hurwitz et al. 1987).

Changes in the Incidence of Reye's Syndrome

By 1987, the incidence of Reye's syndrome had declined to its lowest level since monitoring began in the mid-1970s. The FDA reported in the October 1987 *FDA Drug Bulletin*:

> It appears that the rate of RS has decreased markedly in the U.S., probably as a result of PHS and voluntary industry publicity and educational efforts, and that parents are heeding warnings—including those from health professionals and that on the aspirin product labeling—to avoid giving aspirin to children and teenagers with symptoms of chicken pox or flu. (FDA 1987)

Because of the large number of organizations involved, it is difficult to know with certainty what elements or groups were most effective in changing public and professional behavior to reduce the incidence of RS. A quantitative analysis of the timing and intensity of communications from government, the lay and medical press, industry, and other organizations is crucial to an understanding of the changes that occurred. Although cause-and-effect relationships cannot be shown by

such analyses, it is informative to isolate the "turning point" in RS incidence and compare it with periods of increased intensity in specific types of public communications.

The treatment of influenza and chicken pox frequently involves advice from a family physician or pharmacist, as well as independent treatment decisions by parents. If the campaign was successful, it would have raised the awareness of both health professionals and parents concerning the aspirin–RS link. Several studies have documented a congruence between the government and public health messages and physician knowledge and behavior. For example, in 1986, Rahwan and Rahwan reported that 91 percent of pediatricians and 98 percent of pharmacists no longer recommended aspirin for children with fever or pain, and an almost identical proportion instead recommended acetaminophen (Rahwan and Rahwan 1986). Similarly, an FDA research group used pharmaceutical marketing data to demonstrate that physician prescribing of aspirin to children declined significantly from 1980 to 1985, while acetaminophen prescriptions rose (Arrowsmith et al. 1987). This effect was not significant for adults, suggesting a selective effect of the publicity and warnings on aspirin use in children.

Other studies suggest that parents became aware of the aspirin–RS association during the 1980s. For example, in 1985, Morris and Klimberg (1986) conducted a national telephone survey of 1,155 parents of children under 20 to determine medication use during episodes of influenza or chicken pox. Fifty-three percent of parents surveyed were aware of the contraindications against aspirin use, 40 percent could spontaneously recall the name Reye's syndrome, and 84 percent had heard of RS based on a recognition test. Among the group of children who had chicken pox, about 58 percent of their parents said they gave their child a medication; 54 percent of these medicines were nonaspirin products, and only 6 percent were aspirin. Similar figures were also found for children with influenza.

Although these studies suggest that consumer and professional knowledge and behavior had improved by 1985, it is not clear which public and professional communications were the catalysts for these changes. Because many of the aspirin-labeling requirements and federally sponsored education programs were delayed, we hypothesized that the lay and professional media were the primary mechanisms for educating physicians and parents in the early years of this controversy (1981–1983). In order to better understand these temporal relationships, we

constructed time-series measures of Reye's syndrome incidence and the quantity of lay and medical press reports on this topic, as well as indicators of the timing of major government and private actions or educational programs that might have affected parental and professional behavior directly or indirectly by stimulating media coverage.

Sources of Data on RS Incidence and Media Coverage

Data on the estimated yearly incidence of RS per 100,000 population under 18 years of age from 1977 (when expanded reporting was initiated) to 1989 were obtained from the Centers for Disease Control RS surveillance system (*MMWR* 1989). One threat to the validity of these data is that increased media attention may itself have resulted in more case detection over time. Fortunately for this analysis, however, such an effect would result in positive trends in RS incidence. This effect would, if anything, mask a true association between the quantity of media reports and the incidence of RS.

The MEDLINE system, a biomedical/health care database covering well over 3,000 journals, was used as an index of physician and health professional exposure to original articles, reports, or commentaries on the relationship between aspirin and Reye's syndrome between 1974 and 1989. Two computerized indices were used to examine the quantity of exposure to this topic given by the lay press: the National Newspaper Index™ and the Magazine Index™ of the Information Access Company. We confined our reviews to four continuously reporting major national newspapers: the *Los Angeles Times*, the *New York Times*, the *Wall Street Journal*, and the *Washington Post*.

Any article that included "aspirin" or "salicylates" and "Reye's syndrome" in the headlines, text, or descriptors was counted as one "warning" on aspirin and RS. Inspection of a large sample of medical and lay reports confirmed that virtually all in fact mentioned the possible role of aspirin in causing some cases of RS. The above indicators were not meant to represent all media, as radio and television were also powerful influences on attitudes and beliefs concerning the aspirin–RS link. However, previous studies have indicated that television coverage usually closely parallels newspaper coverage (Winsten 1985).

Association of Media Reports and RS Incidence

Figure 1 indicates the trends in the number of medical citations, newspaper and magazine reports, and the incidence of RS from 1974 to 1989. Until 1980, very little medical reporting on this relationship was observed, except for a small increase in the number of medical reports in 1976 coinciding with the initial FDA bulletin suggesting the possibility of a relationship between aspirin use and Reye's syndrome. The number of medical citations increased suddenly from four in 1980, to eight in 1981, to between 20 and 30 per year from 1982 to 1988. Interestingly, the trends in newspaper and magazine citations were similarly flat at close to zero during the years 1979 to 1980 and, like the medical reports, first peaked in 1982 at over 30 citations.

Although we did not conduct formal content analyses of newspaper

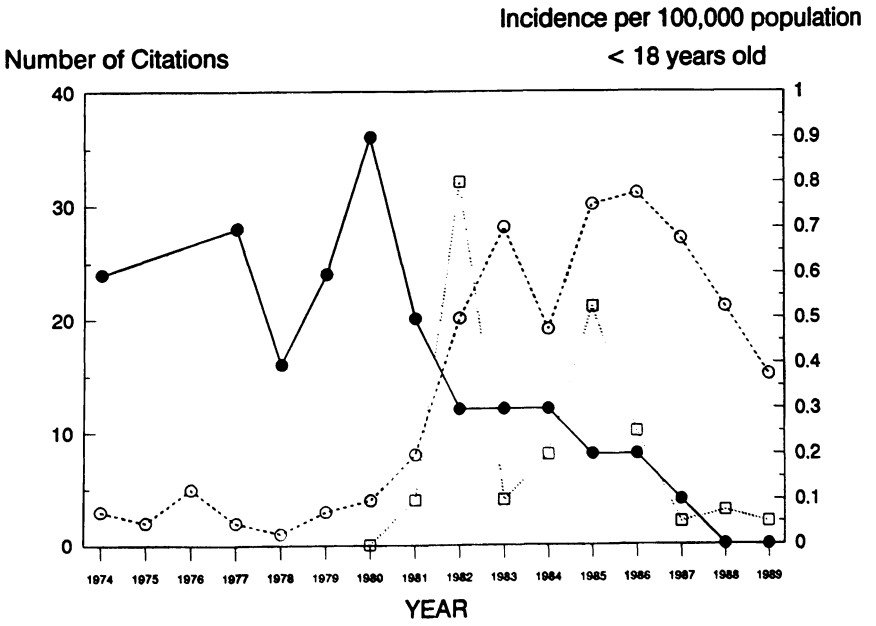

FIG. 1. Trend in number of medical and lay press citations on aspirin and Reye's syndrome, and in incidence of Reye's syndrome among children. Newspaper index limited to four continuously reporting national newspapers described in text. —●—, incidence of Reye's syndrome; --o--, medical literature citations; --□--, newspaper and magazine citations.

and magazine reports, a review of a sample of these stories conveyed several general messages that tended to recur in each time period. During 1982, the first major spike in lay media coverage, the stories covered government, industry, and consumer responses to the initial state studies, labeling delays, and pressures on the FDA to take stronger actions. Other reports covered proposals for warning labels on aspirin containers, industry opposition to these proposals, and government announcements of the need for new federally sponsored studies. For example, under the headline "Warning Issued on Giving Aspirin to Children," a June 5, 1982 article in the *New York Times* gave a clear warning at the same time that it reported early government plans to deal with the issue:

> The Government announced plans today to advise doctors and parents against using aspirin to treat children's chicken pox or flu-like symptoms because studies have linked aspirin to Reye's Syndrome, a rare but often fatal children's disease. (Hinds 1982b)

In a more vivid, personal, and compelling story told on the CBS Evening News Dan Rather introduced the issue to millions of Americans:

> Another childhood killer is called the Reye's Syndrome, which attacks the brain and liver. When children run high fevers, most parents reach for the aspirin bottle right away. But now there's some concern that when the fever is brought on by the flu or the chicken pox, aspirin can actually produce the Reye's Syndrome. This disease is not always fatal, but Meredith Vieira has the story of one little girl who did not survive and of the role aspirin might or might not have played. (Rather 1982)

In 1983, the media continued to cover the battles between the consumer groups and the aspirin industry, as well as to provide investigative reports on the reasons for halting labeling requirements. On November 30, 1983, the *New York Times* ran an article with the following headline: "U.S. Puts Off Aspirin Warnings" (*New York Times* 1983). On the same day, the *Washington Post* ran its article on the decision of the Reagan administration to halt the distribution of 500,000 warning pamphlets in supermarkets (Atkinson 1983). Although these reports often focused on controversies and accusations, they also continued to alert the public and professionals to the strong possibility that aspirin could cause Reye's syndrome in children.

The coverage during the second "pulse" of news reporting (winter/spring 1984–1985) focused on the results of the CDC pilot study linking aspirin with RS. Other articles covered DHHS secretary Margaret Heckler's call for voluntary labeling of aspirin products, and charges that the aspirin industry attempted to slow the spread of warning information. One example is an article in the December 15 issue of the *New York Times*:

> Some time in early spring, a federal regulation is expected to go into effect that will require all packages of aspirin or medicines containing aspirin to carry a warning about a childhood disease. . . . Dr. Sidney M. Wolfe, head of the Health Research Group . . . said his group had petitioned for it 3 1/2 years ago. . . . If mandatory warnings had been in place on all aspirin products several years ago, the toll of death and brain damage would have been much lower. (*New York Times* 1984)

When the pilot study was completed, a January 9, 1985 *Los Angeles Times* story led with the following:

> A new federal study has found such a strong association between the use of aspirin in children and the often-fatal Reye's Syndrome that scientists are expected to call for an immediate warning against the drug's use on ill youngsters. (Cimons 1985)

A front-page report published by the *Boston Globe* on January 17, 1985 implied that the aspirin-industry-financed organizations (e.g., the CCC) slowed the government's response to the aspirin–RS link:

> In 1981, federal health officials . . . concluded that there was a link between aspirin and Reye's syndrome. . . .
>
> But it was not until last week that the Secretary of Health and Human Services, Margaret M. Heckler, asked that aspirin products be labeled to warn against the danger to children. . . .
>
> In the intervening three years, . . . the aspirin industry has repeatedly frustrated attempts by health officials to warn the public of the dangers, insisting—with some support in the medical community—that the studies were flawed. . . .
>
> According to Globe interviews with medical and government officials involved in the controversy, the industry has used its access in the deregulation-minded political corridors of the Reagan Administration to help block mandated labeling of its product. . . . (Robinson 1985)

Finally, at the end of this year, a series of articles discussed the required labeling to go into effect in 1986.

It is interesting to note that the initial cautionary statements made by the FDA in 1976, and the CDC in 1980, were not clearly associated with any changes in disease incidence (see figure 1). However, the broad media coverage stimulated by the publication of the three state studies, the CDC's committee report in 1982, and government and private statements on the issue, coincides with a sudden and consistent downward trend in Reye's syndrome incidence.

Before 1981, the yearly incidence of Reye's syndrome ranged between .3 and .9 cases per 100,000 population under 18 years of age. These swings in incidence rates have been found to correspond with high or low incidence rates for influenza A and varicella in the United States (Barrett et al. 1986). Coincident with the sudden increase in medical and lay press reports in 1982, the incidence rates of Reye's syndrome fell to their lowest level and remained stable for three consecutive years. The second peak in lay press reports in 1985 began a period of further decline, at the end of which incidence of RS had declined to only 25 cases per year (a rounded incidence rate of zero per 100,000).

Conclusions

Our analysis suggests that the professional and lay media were important communication channels in alerting health professionals and parents about the relationship between aspirin and Reye's syndrome, particularly during the early years of the controversy (1981–1983). The nationwide decline in disease incidence coincided with declines in the use of aspirin for childhood fevers, and provides further evidence of the validity of the epidemiological studies reporting the aspirin–RS link.

Interestingly, in view of the fact that warning labels were the subject of the most controversy, by the time aspirin product labeling was required in 1986, a large part of the decline in RS incidence had already occurred. At the same time, it is likely that the continuing education and labeling changes have probably served to maintain and reinforce the new behaviors after the lay press discontinued its reporting of this topic in recent years.

How can we explain the success of this largely media-based health communications campaign, given the inconsistency of previous mass media campaigns in changing human behaviors? For example, the Stan-

ford Three Communities Study (TCS) found that mass media alone was relatively unsuccessful in achieving long-term changes in cardiovascular risk behavior until it was supplemented with face-to-face counseling (Farquhar et al. 1977). Similarly, mixed results of media-only interventions have been reported for smoking behavior (Flay 1987).

Part of the explanation of the success of the RS risk communications is the simplicity of the problem and desired behaviors in comparison to more complex habit-driven behaviors like smoking and exercise, which are resistant to change by information alone. Previous analyses have correlated increased pill and IUD discontinuation rates for five to six months following unfavorable news stories about these birth control methods, partly as a result of the availability of alternative techniques (Jones, Beniger, and Westoff 1980). In the present analysis, parents (or their physicians and pharmacists) simply switched from aspirin to acetaminophen (e.g., Tylenol) when treating symptoms of flu or chicken pox; the latter medication is equally available and inexpensive, so no barrier other than habit existed to its use. Given the nature and severity of the illness, simple information provision could induce change without the need for altering underlying motivations.

The aspirin–RS link was especially newsworthy given the combination of a rare, uncontrollable but serious disease affecting a highly valued, vulnerable population, linked to a common, over-the-counter product. The maneuverings of the aspirin industry, medical profession, government health agencies, and community watchdogs kept the issue alive for a number of years. This resulted in widespread and *repeated* exposure by television, radio, and print media, as well as in professional journals over a short period of time.

Another key ingredient was the comprehensiveness of the communications (Pasick and Wallack 1988–89), involving multiple communication channels to reach various target audiences, including parents, physicians, pharmacists, and other health professionals. These multiple levels of reinforcement increased the probability that a given parent, consulting with these professionals, would obtain advice to give acetaminophen instead of aspirin to children with flu or chicken pox. For example, the study by Morris and Klimberg (1986) suggests that over half of 1,155 parents would only give medications recommended by their physician for treating these conditions.

This case study also focused on one potential obstacle to effective risk communication—counteradvertising by an industry-based health orga-

nization, the Committee for the Care of Children. In situations when conflicting health messages are communicated to the public, there is less likelihood of achieving desired behavioral objectives. In this case, however, the conflicting messages may not have affected public attitudes toward the credibility of government warning messages because of the energetic work of the HRG and others in strongly discouraging networks from airing industry-based PSAs.

Another important issue was the inability of government agencies to state warning messages conclusively and understandably at a time when there was still uncertainty about the scientific validity of the epidemiological studies. Combined with the pressures of legal suits from the aspirin industry, these factors led to some overly scientific and circumspect public communications. For example, the 1985 government radio and TV PSAs carried the following language:

> A rare but serious childhood disease called Reye's Syndrome may develop in children who have chicken pox or flu. Although the cause of RS is not known, some studies suggest a possible association with medicines containing salicylate or aspirin. So it is prudent to consult a doctor before giving these medicines to children and teenagers with chicken pox or flu.

Legal requirements to use words like "association" and "salicylate" may have reduced the comprehensibility of key messages and the resulting impact of the FDA messages. The lay press, on the other hand, was more flexible in publishing warning messages in less ambiguous terms. For example, one headline appearing in the *Washington Post* on February 11, 1982 stated: "Children With Chicken Pox, Flu Shouldn't Use Aspirin, U.S. Says." Similarly, on April 28, 1982, the *New York Times* headlined an article, "Aspirin Linked to a Children's Disease" (Hinds 1982a).

Although the number of Reye's syndrome cases has declined dramatically, one issue has not been addressed adequately in the existing literature: to what extent did aspirin use decline in individuals who benefitted substantially from this medication (e.g., juvenile rheumatoid arthritis, adults with angina) and who are not at risk for Reye's syndrome? In other words, did the media campaign selectively affect the target population (children and adolescents with chicken pox and flu), or did these effects spill over into other nontargeted conditions and groups? This must have represented a key concern of industry when re-

sponding to the pressure for warning campaigns and labeling changes. Potential public overreaction to a concern about the risks of aspirin use threatened sales of a product that was not only profitable, but of great clinical value. The evolving stance of the aspirin industry indicated both their acceptance of the validity of repeated epidemiological findings, and also their confidence that aspirin use for other indications would not decline precipitously.

Can we generalize from this experience to other types of public health warning campaigns? In situations when a common product could be causing a rare but devastating illness, where the behavior change message is simple and clear, and where safer and inexpensive alternative products are equally available and acceptable, it appears that a media-based educational campaign directed at both consumers and providers through multiple channels can facilitate substantial changes in behavior, even in the absence of product warnings or active industry acceptance. The sharp decline in U.S. sales of apples and apple juice following widespread publicity about the dangers of the chemical Alar (Shabecoff 1989) provides a similar example of the power of the lay press in shaping consumer behavior. Consumer groups can and should play an important role in hastening public action and in keeping well-validated health product risks media worthy.

In the absence of future controversies about the link between aspirin use and RS, which might precipitate more media coverage, it will be interesting to observe whether the new behaviors will continue, fostered only by professional and public memory of the issue and the continued presence of product warnings.

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