"A very thoroughly researched and truly fascinating history."
—Uwe E. Reinhardt, *New York Times Book Review*

THE Aspirin WARS

Money, Medicine, and 100 Years of Rampant Competition

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Mark L. Plummer

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MONEY, MEDICINE, AND 100 YEARS OF RAMPANT COMPETITION

by CHARLES C. MANN
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ALSO BY CHARLES C. MANN

The Second Creation:
Makers of the Revolution
in Twentieth-Century Physics
(with Robert P. Crease)

THE ASPIRIN WARS

To my family, with lots of love
—C.C.M.

To Cassie, Robert, and Elizabeth,
who all helped
—M.L.P.

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THE ASPIRIN WARS

PROLOGUE

"HOW ON EARTH DID ALL THIS COME ABOUT?"

At ten o'clock in the morning of March 2, 1988, forty people filed into a conference room adjacent to the fourteenth-floor office of Frank Young, M.D., Ph.D., the commissioner of the U.S. Food and Drug Administration. Anything but the sort of august, wood-paneled study seen in the movies, the conference room had a Formica-topped oval table, the Stars and Stripes and a few other flags, two screens for projecting slides, and a window overlooking Parklawn, a big cemetery northwest of Washington, D.C. The meeting was crowded, uncomfortably warm, and, for many of the participants, rather glum. They were about to get a lesson in the way big business and big government interact, and they suspected they were not going to like it. Indeed, they feared they were about to lose a market worth hundreds of millions of dollars every year.

Affable, plump, bespectacled, Frank Young took his position at the head of the table. Despite his credentials as a conservative Republican and a born-again Christian, Young was the antithesis of the Reagan administration's professed hostility toward government. The FDA is the branch of the Department of Health and Human Services that oversees the food and medicine sold in the United States; because of its reputation for toughness, it serves as a bellwether to its sister bodies in governments across the Atlantic and Pacific. In keeping with this image, Young liked to describe his agency as the cop on the beat, patrolling the lucrative world of big drugs. Although the yearly sales of the firms represented in Young's office that morning dwarfed his agency's budget, the executives around the table took the commissioner seriously indeed. With little in the way of preliminaries, the FDA has the authority to declare that a drug company's products are "misbranded"—sold as something they are not—and order them pulled from store shelves. In addition to costing millions in sales, misbranding actions generate a black cloud of negative headlines that can take months to

dispel. Moreover, many pharmaceutical companies believe, the agency is often not satisfied until it has seen a few heads roll.

The businesspeople—presidents, general managers, and sales directors—in Young's conference room came from a select group: Their companies sold aspirin.* Five weeks before, on January 28, the *New England Journal of Medicine*, perhaps the most important and certainly the most visible biomedical journal in the United States, had published a preliminary report that aspirin could greatly lower the chances that an adult male would fall victim to a heart attack. Heart attacks are the leading cause of death in the Western world. In the United States alone, they kill more than 500,000 people a year. Stroke, an allied syndrome, annually takes another 150,000 souls. If, as the study suggested, a tablet of aspirin every other day could prevent a fifth of these deaths, at least 130,000 lives a year would be spared. In terms of annual mortality, this would be equivalent to wiping out AIDS in this country three times over.

The aspirin manufacturers greeted the report as a godsend. Aspirin is the most widely taken drug in the world, and has been for decades. In the United States alone, thirty billion tablets are consumed every year. Worldwide the figures are less certain, but a plausible estimate is that one hundred million pounds of aspirin disappear annually in the course of relieving headaches, reducing fevers, and soothing rheumatic pains—a small mountain of little white pills. Nonetheless, aspirin makers had long been unhappy. The market for headache remedies was now dominated by newer products like Tylenol (made from a different drug, acetaminophen) and Advil (made from ibuprofen), whose corporate parents spent vast sums on television advertisements proclaiming that they were safer (Tylenol) or more powerful (Advil) than aspirin. In recent years, moreover, a deadly but extremely rare children's disease called Reye's syndrome had come to be associated with aspirin, and the FDA had required a stiff warning notice to be printed on the bottle. Fearful of Reye's syndrome, many families stopped buying aspirin—so many that the children's aspirin market collapsed.

All this seemed about to change. Evidence of aspirin's beneficial effects had been accumulating for years, and in 1984 the FDA approved its use by patients who had suffered a previous heart attack, as well as for victims of some types of stroke and angina pectoris (chest pains due to oxygen deprivation in the heart). The *Journal* report was qualitatively different. It was the first scientific evidence that aspirin could reduce the chance of heart attacks in healthy people. Aspirin, in short, was not just for those unlucky enough

* In some nations, such as the United States, the United Kingdom, and France, aspirin is the common name for the chemical acetylsalicylic acid, and any company may use that name to describe its product. But ASPIRIN® is a registered trademark of Bayer AG, Germany, in approximately seventy countries worldwide. And in Canada, it is a registered trademark used exclusively to identify analgesics manufactured and distributed by Sterling-Winthrop, Inc.

already to be sick but also for the millions upon millions of people who *might* get sick.

Aspirin companies envisioned their humble pill, in the language of marketing, "repositioned" as a high-tech heart attack preventive. If half the men in the United States took an aspirin tablet every other day, annual aspirin sales would go up by $600 million, a 75 percent increase. Add foreign sales to that and the figure grew even more pleasing to contemplate. Moreover, those hundreds of millions would not be a one-time gain but would roll in year after year until the distant day when someone invented a cure for heart disease. Only one obstacle stood in the way of this rosy future: the FDA, with Frank Young at its head.

Of the ten aspirin companies at the meeting, the one with the most to lose was Sterling Drug, a New York City firm that, when the *Journal* article appeared, was in the process of being acquired by Eastman Kodak. Sterling makes Bayer aspirin, for seventy-five years the most familiar brand in the United States. Constant promotion has made Bayer's name and slogans ("Pure aspirin, not part aspirin," "Nine out of ten doctors recommend") synonymous with the drug. "For better or worse, we have a lock on it," Sterling research director Earle I. Lockhart explained not long ago. "The Bayer name lives and dies by aspirin."

Sterling had long been interested in aspirin's effects on cardiovascular disease. Without explicit approval from the FDA, it had broadcast television commercials about aspirin and second heart attacks for much of the past year. As part of this campaign, the firm had just produced its first "Calendar Pak"—a month's supply of aspirin dispensed like birth control pills, in a container with pouches labeled for each day, meant to be sold directly to the public. As the first Calendar Paks appeared on store shelves, company executives were elated to learn that the *New England Journal of Medicine* was set to publish a major new study on aspirin.

Known as the Physicians' Health Study, the medical experiment was one of the largest ever conducted, involving some 22,000 volunteers. Half took an aspirin every other day; the other half took a placebo—a pill that resembled an aspirin tablet but had no effect. For four years, a committee of doctors monitored the participants' health, looking for anything unusual. In December 1987, they found it: The group taking aspirin experienced 40 percent fewer heart attacks than the group taking placebo. Faced with this amazing difference, the doctors halted the experiment three years early, rather than continue giving placebo to participants who should be taking aspirin. And they contacted the *New England Journal of Medicine* to arrange expedited publication of the results.

Because the *Journal* refuses to print any material that has been described

elsewhere, newspapers, magazines, and television networks usually agree to hold their stories until the day subscribers receive their copies. The Physicians' Health Study was stopped in mid-December; the printing of the preliminary report by the committee could not take place before mid-January. Sterling thus had a month to assemble a promotional blitz before the aspirin report was trumpeted by the media. Working night and day, the company kicked off its campaign at the earliest moment that would avoid the *Journal*'s wrath: 6:00 P.M., Wednesday, January 27, 1988—just in time for the evening news.

The coverage was everything Sterling could have wanted. "One aspirin every other day," *NBC Nightly News* anchorman Tom Brokaw told millions of viewers. "This simple prescription . . . dramatically reduce[s] heart attacks in men." The network cut to science correspondent Robert Bazell. "Many health officials see the results of the aspirin study," Bazell said, "as some of the best news ever about preventing heart attack." He interviewed Bernard Kabakow, a doctor who participated in the study. "In theory," Kabakow said, "as many as a hundred thousand or more [people] per year may have their heart attack prevented by the administration of an aspirin tablet every other day." Similar coverage appeared on the other two major networks, and on local news programs across the United States.

The study was splashed over the front pages of the *New York Times* and the *Washington Post* the next morning. Bryant Gumbel put aspirin on *Today*, the most popular morning news show, asking the study's director, Charles Hennekens of the Harvard School of Public Health, if "every male over the age of thirty-five should be doing it [taking aspirin]." (They should ask their doctors, Hennekens said.) Extra Bayer commercials blanketed network news programs throughout the day.

On January 29 Sterling took out full-page ads in newspapers across the nation. "Good News for Heart Health in America," inch-high letters proclaimed. Below, in slightly smaller type, was an unadorned column of print:

> A major study sponsored by the National Institutes of Health showing that an aspirin taken every other day helped prevent first heart attacks was reported this week in the *New England Journal of Medicine*. . . . Although not yet reviewed by the FDA, [the study] is further evidence that aspirin therapy for cardiovascular disease greatly advances the progress of heart health in this country. The Bayer Company will continue to make major commitments to finding innovative ways to better the heart health of America. Ask your doctor about aspirin therapy to help prevent heart attacks.

As self-promotion, the advertisement was modest. It presented an accurate summary of the results, gave the source of the report, emphasized that it was

not yet reviewed by the government, and told potential users to call their doctors. The tone was conservative, even cautious. "This is *medicine*," Lockhart said later. "We aren't selling toothpaste."

The FDA telephoned the next day. "Good News" had to stop.

Aspirin makers have a remarkable, perhaps unique, history of competition; they have been slugging it out over exactly the same ground since the end of the First World War. The market for pain relievers—analgesics, as doctors call them—is well worth the effort. In 1990, Americans bought about $2.7 billion worth of analgesics, fully a quarter of the over-the-counter drug market, and more than the total for shampoos, deodorants, toothpastes, or any other single category of health and beauty products. Because the price of a pill is roughly ten times the cost of its active ingredient, the $2.7 billion leaves a hefty chunk for packaging, distribution, advertising, and, of course, profit. To make that profit, some aspirin firms sell pure acetylsalicylic acid (ASA), the scientific name for the chemical known as aspirin; others add ingredients such as caffeine and antacids; still others wrap the ASA in a special coating. Because ASA has remained unchanged since its invention in 1897, however, all aspirin brands, no matter how new and improved, have the identical active ingredient, and medical science has yet to show that any of these fancy versions are better than aspirin alone for headaches, fever, and inflammation.

In capitalist societies, such a situation—companies selling equally effective products with big potential profits—virtually guarantees furious competition, the type Adam Smith had in mind when he wrote of the awesome powers of the "invisible hand," the free market. And, indeed, the ten firms at FDA headquarters that morning have a record of industrial warfare that could serve as a chapbook to the means, honest or unscrupulous as they may be, by which modern corporations vie for superiority. Their struggle provides a vest-pocket history of the mixture of marketing, litigation, technology, and competition that characterizes so much of business, and of life, in this century. Another way to put it is that the annals of aspirin give a glimpse of the incredible lengths to which people will go to put something in a box and sell it.

Given this history, Sterling's competitors were not going to let it steal a march on them. Most of them in the past had emphasized the difference between their products and unadorned ASA, which meant that their brand names were not clearly associated with aspirin. Now that aspirin was headline news, Sterling's rivals were pushed into making stronger claims than those made for Bayer to compete on this shifting ground. Inevitably, one of them went too far, which is why they all ended up in the office of Frank Young.

The culprit was Rorer Consumer Pharmaceuticals, of Fort Washington, Pennsylvania, maker of a little-known brand named Ascriptin, a mixture of ASA and Maalox, the latter being a popular antacid that is added to alleviate the irritating effects of aspirin on the stomach. Until the Physicians' Health Study, the brand had primarily been marketed to doctors with patients who took large doses of aspirin to relieve arthritic pain. When the aspirin–heart attack story appeared on the evening news, it occurred to Rorer that Ascriptin might be a winner. If people began using aspirin to protect their hearts, they might want to protect their stomachs at the same time.

On February 10, Rorer, like Sterling before it, took out a full-page ad in the *New York Times*. Under the headline THE ASPIRIN YOU CAN LIVE WITH, it depicted the front page of the January 28 *Times*, folded to show the article that reported the Physicians' Health Study. "This may be the most important ad you'll ever read," the copy declared.

> A single aspirin tablet every other day can cut a man's chances of getting a heart attack almost in half, according to a major new study.
>
> But it can also upset your stomach.
>
> So ask your doctor about Ascriptin. The aspirin you can live with.

Beneath it was a coupon ("This may be the most important coupon you ever clip") for Ascriptin. This was Rorer's bid to seize a greater share of the market. The campaign, it declared, would go on for weeks and involve considerable expense.

Hours after the publication of the ad, Rorer received a call from the Federal Trade Commission, the agency that regulates most forms of advertising. Gamely describing the conversation as "cordial," the firm announced it would cut short the campaign, although ads would still appear in the next issues of *Time* and *Newsweek*. On February 11, the offices of the attorneys general for Texas and New York sent a joint letter to Joseph E. Smith, the president of Rorer Consumer Pharmaceuticals. The letter was not cordial; it demanded that Rorer "cease and desist from any further placement of this or any similar advertisement." To make matters clear, the attorney general of Texas publicly threatened to sue. Several days after that, Rorer and nine other aspirin firms were asked to meet with Frank Young.

In some respects, the FDA's summons was a minor victory in a fifty-year battle over what Young has described as "the nastiest four-letter word: turf." Drugs are divided into two categories: prescription drugs, which are sold only at pharmacies to patients with orders from doctors; and over-the-counter drugs, which are sold almost anywhere. The Food and Drug Administration regulates the advertising of prescription drugs, whereas the Federal Trade

Commission regulates the advertising of over-the-counter drugs. The labels and package inserts of both prescription and over-the-counter drugs, however, are under the purview of the FDA, which means that one agency (the FDA) oversees what firms may claim about over-the-counter drugs on the label, and another agency (the FTC) oversees what they may claim about over-the-counter drugs in the advertising. The FDA bristled for years at this division of labor. "What the agency did with that," Peter Rheinstein, FDA director of medical staff in the Office of Health Affairs, said recently, "is to say that products advertised in ways inconsistent with their labels are misbranded, because the label fails to bear adequate directions for the advertised use." This allows the FDA to yank the drug from the market—thus giving it a *de facto* control of advertising that it is denied *de jure*.

Unsurprisingly, the FTC has vigorously resisted this usurpation of its powers. But it has received less than enthusiastic support from the companies involved. All drug makers must gain FDA approval to market new medicines, which have to be tested for safety and efficacy in a process that takes years and millions of dollars to complete. "Few people want to risk getting in its bad graces," said one pharmaceutical executive whose company avoids struggles with the agency. "Nobody wants to find that it takes the FDA's scientists an extra five years to go through your drug applications."

Aspirin is a regulatory rarity, in that it is treated as both an over-the-counter and a prescription drug. For headaches, fevers, and minor inflammation, aspirin makers can tout their product to the public under the scrutiny of the FTC; heart attacks, though, are the type of serious ailment that usually places a drug and its promotion under the purview of the FDA. Advertisements about the Physicians' Health Study thus straddled the blurry dividing line between the FDA and the FTC. After a call from Young, the FTC reluctantly let its rival agency lead the way.

Aspirin might indeed be a winner, the FDA admitted, but it did not want the firms to blare the news to the public. The study's final report was not yet published or even written; questions about side effects still had to be answered. On this skimpy evidence, the FDA was loath to endorse the idea of aspirin as a heart-attack preventive. In addition, even if the Physicians' Health Study ultimately turned out to be convincing, the agency was not sanguine about companies advertising on television that taking a pill might cut the risk of heart attack almost in half. As far as Young was concerned, people were going to learn about aspirin from their doctors, who could give them accurate information on the risks, and not from the commercial breaks on *The Cosby Show*. And that was just what he intended to tell the assembled aspirin manufacturers, regardless of the legal niceties.

The aspirin companies thus found themselves in a predicament. Frantic to seize the opportunity to recapture a lost market, they were being warned not to publicize a scientific study that was already on the front pages of news-