

Philip J. Hilts (2003), "Epilogue: Greed and Goodness" in *Protecting America's Health The FDA, Business, and One Hundred Years of Regulation*. New York: Alfred A. Knopf, 338-343.

In looking over the history of food and drug regulation, and the little agency that was created in the progressive years, there is one story that for me, still stands out. It is the tale of the drug called Panalba.

The drug, made by the Upjohn Company from 1957 to 1970, was an antibiotic combination measurably less effective than other antibiotics on the market at the same time for the same uses. Some patients who took Panalba instead of one of its competitors simply didn't get better as they should. In the worst cases, that led to permanent injury or death, the FDA and, independently, the National Academy of Sciences said the drug had no use in modern medicine.

But Panalba was a big seller for Upjohn, yielding 12 percent of the company's entire gross income. Doctors who should have known better had been persuaded by company salesmen that by giving two drugs in one, they were giving better therapy. So, despite the clear judgment of medical science, and despite clear evidence that some were suffering needlessly, and while the FDA sought a ban, the company kept Panalba on the market. In fact, Upjohn knew of the problems before they became public, and had concealed them. Now, every additional month of sales before Panalba was forcibly pulled from the market meant an additional million dollars. The company's decision was supported by the American Medical Association. Its leaders acknowledged that the drug was not a good one, but the AMA said it was important to assert the authority of doctors rather than government regulators over the health of patients. They must be able to prescribe any medicine, even a bad one, if they choose.

There was an essential conflict: on one side, solid scientific data supporting a policy judgment; on the other side, two powerful special interests. The company intervened politically

and twisted arms in government to derail any FDA action. There was a deadlock. Faced with the evidence and the public requests from some scientists to stop selling the drug, a special board meeting was called at Upjohn. The board chose not only to keep the dangerous drug on the market, but to vigorously fight in court to keep it available as long as possible.

When Professor J, Scott Armstrong, a teacher of management at the Wharton School at the University of Pennsylvania, read a story by Morton Mintz in *Science* magazine about this fiasco, he was struck by the behavior of the Upjohn managers during their crisis. Armstrong's students were all bright prospective managers of American business or prospective teachers of the theory of business. They were in his classes to learn how to think about managing businesses effectively. When he finished Mintz's article, Armstrong said, "I thought, well, I don't believe my students, faced with that situation, would have acted the way Upjohn did. I just don't think so." He asked his students if they had ever heard of the case; they said no, So he designed a little experiment to test his faith.

First, he described the case to a sample of seventy-one students and businessmen and told them of Upjohn's choice to keep Panalba on the market, and further, to fight in court to keep it on the market, and to lobby behind the scenes in Washington to defeat the FDA. He asked them whether Upjohn acted in a socially responsible manner. Not one of those asked counted Upjohn's behavior as socially responsible. Ninety-seven percent said it was irresponsible, and 3 percent offered no opinion.

It seemed clear enough; this was business behavior that was out of bounds. Then Armstrong asked a different group of students to act out the situation in a brief role-playing episode. Each was to take a role as one of the seven members of the Upjohn board of directors. Each player was told that the FDA wanted to remove the drug from the market as a hazard, and that that decision

was based on a twenty-year study and a conclusion by an unbiased group of medical scientists whose recommendation was unanimous. The “board” was given other information about the company’s profits and revenues from the drug, then met for forty-five minutes to make one of the following decision : (1) recall Panalba immediately and destroy it; (2) stop production of Panalba immediately, but allow what had been made to be sold; (3) stop all advertising and promotion of Panalba, but provide it for those doctors who request it; (4) continue efforts to market Panalba most effectively until sale is actually banned; and (5) continue efforts to market Panalba most effectively and take legal, political, and other necessary action to prevent the authorities from banning Panalba.

Playing the role of Upjohn board members instead of simply judging them, 79 percent of the students came to the same decision as Upjohn – number five. Armstrong tried again. With another group, he made it crystal clear to those playing Upjohn managers that the product was killing a number of people every year, and cured infections no better than several similar products that were safer. Adding this information changed little; three-quarters of the students chose to keep up sales as long as possible to earn \$19 million a year from the drug.

“I was stunned;” said Armstrong. “My students were making the same decisions Upjohn had, even when it was laid out clearly that patients were dying. No matter how I put the case, hardly anyone decided to take the drug off the market. In one case, I even arranged for someone to rush into the meeting, and say, ‘I’m the research director. Our own studies were suppressed until now and they show that they are right, this drug is killing people.’ Even that didn’t do it.”

Armstrong was not the only one surprised; those who participated in the experiment were dismayed with their own behavior after they realized that the experiment had not been simply a

teaching exercise about decision-making in a crisis, as it had been presented, but a measure of social responsibility.

The results were so unexpected to Armstrong that he decided to continue the experiment. Thus began years of repetitions and variations of what he had seen but had difficulty believing. Was this really the way people behave when it is their role to be a manager, in apparent disregard of their social responsibility? He asked other researchers to carry out versions of the experiment. The experiment was also conducted in other nations, and among role players of different ages and experience. The results held firm.

Armstrong focused on what he felt was the key issue – what the “board members” thought their role was. In America and, in recent times around the world, the standard belief among business managers is that they should work to maximize profits, and let the market take care of the social outcome of their choices. The idea has been most famously expressed by the barons of commerce themselves. William K. Vanderbilt, asked about the harm to the public of his closing a railroad line, replied, “The public be damned! I am working for my stockholders!” This view, in less harsh words, is strongly supported by the teaching of business schools and the strong “free-market” culture that has developed in business. It is the standard view, explicitly stated by many companies and found in polls to be the majority opinion of businessmen. In fact, it has often been said that the business manager’s duty is only to the stockholder. This, of course, relieves the manager of the responsibility to think about society in general. Furthermore, the attitude has been repeatedly backed up in the view of courts since the 1920. In other words, as Armstrong notes, air pollution is acceptable if it represents no threat to profit maximization. Only a boycott triggered by reports of pollution from a company should get the manager’s attention.

In later versions of the experiment, Armstrong asked the players to consider not only stockholders' interests but also the interests of a few other specified groups directly affected by the directors' decisions. They were asked not to think of the interests of society in general, but to weigh the effect of their decisions on stockholders and on company employees, customers, retailers, and the community where the company is located – the “stakeholders.” This had no significant effect. Seventy-six percent chose the most irresponsible course, and none chose to take the hazardous drug off the market.

Trying yet another approach, Armstrong imagined a situation that exists in a few Swedish corporations. Armstrong altered the composition of the “Upjohn” board to include a public representative, an employer representative, and a supplier representative. This, finally, had an effect on the outcome. Adding stakeholders to the board and providing a specific accounting of the possible harm their decision could have, board members voted quite differently. Only 22 percent chose the most irresponsible course. Fifty percent chose a middle course, such as marketing and promoting the drug until an FDA ban took effect. Still, only 29 percent chose to make the moral choice to take the drug off the market.

The experiment was repeated 91 times, in 10 countries, with 2,000 subjects and 23 different experimenters. If the membership of the company's board was not artificially altered to include outsiders and specific details about harm were not given, in North America and Europe, 76 percent of the board members took the most irresponsible course. None chose the most responsible course.

Some years before Armstrong's odyssey, Stanley Milgram of Stanford University carried out a series of experiments testing how much harm people would do to their fellow citizen if asked to by a figure of authority. Milgram devised a simple test. One subject, the “learner,” would be

asked questions. A second, the “teacher” would put the questions. Each time the learner gave a wrong answer, the teacher would administer an electric shock. The shock was mild at first. But as the number of wrong answers from the learner increased, the shocks became more powerful. What the teacher did not know was that he or she was the only subject in the experiment. The learner was in league with the psychologist running the experiment, instructed to give wrong answers on a schedule.

Milgram expected that none of his recruited teachers would actually deliver the most dangerous shocks. He guessed they would tell the attendant psychologist that they would not participate after a certain level. But it did not happen. The teachers jolted the learners up to the limit with hardly a hesitation.

Milgram watched the episodes with surprise, as Armstrong did later when observing his own experiments. Milgram was viewing something about human behavior that was simply not entertained in current psychology. Good people will behave badly as they perform their expected roles..

But we do not need to confront the worst implications of the work of Milgram and Armstrong to understand their meaning for regulation. In reflecting on human history, it is not hard to see the fundamental lesson. As people become more distant from those affected by their decisions they can lose the personal and moral sense of what they are doing. In Milgram’s words, “Ordinary people, simply doing their jobs, and without any particular hostility on their part, can become agents in a terrible, destructive process- Moreover, even when the destructive effects of their work become patently clear . . . relatively few people have the resources needed to resist authority.”

This is the reason for regulation. We must recognize the roles business managers are required to play, and simply set in counterposition to them a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups whose first job is safety. It is, after all, common sense. Warren Kiefer, a public relations executive for Pfizer International, several decades ago spoke before Congress, and then wrote, in a letter to *Saturday Review*, “It was my experience in the drug industry that most executives were honest most of the time. But they were businessmen, who, in the old American tradition, placed company interest first. Public interest was the FDA’s lookout;” he said. “It is the regulatory officials who are responsible to the people.”

In contrast to the FDA’s poor resources but dedication and openness, American corporations overall have failed to evolve much as organizations. They have remained rigid hierarchies, with little input from the public or stakeholders when key decisions are made. Some management experts have begun to press for more open corporations, ones that include as members of the board some workers or members of the communities where the companies reside, or suppliers. Essentially, though, the logic of “profit alone” that dominated the companies in the nineteenth century dominates them today. This is one reason the FDA’s job is difficult and necessary.