

Litigation Causes Huge Price Increases in Childhood Vaccines

Citing the increasing cost of litigation, the two manufacturers of the childhood vaccine DPT announced recently that they are raising their prices substantially. Once again, the costs of litigation are hitting home.

DPT vaccine, which protects children against diphtheria, pertussis, and tetanus, has long been controversial. The problem is that the pertussis part of the vaccine is a crude preparation made from whole bacteria and can, on rare occasions, cause serious complications, including brain damage or death.

According to Alan Hinman of the Centers for Disease Control (CDC), 1 in 310,000 doses of the vaccine causes permanent damage. Eighteen million to 20 million doses are sold in the United States each year. Pertussis, or whooping cough, is even more dangerous than the vaccine and so the administration of DPT vaccine is mandatory in virtually every state. Parents whose children are injured by the vaccine argue that their children should be compensated. The parent group, Dissatisfied Parents Together or DPT, points out that lawsuits are their only means of getting compensation for vaccine-induced injuries.

DPT lawsuits are a relatively recent phenomenon, according to Hinman who has just completed a survey of DPT litigation. One suit was filed in 1978, but 73 were filed in 1984, following widespread publicity over the hazards of the vaccine. In 1985, 219 suits were filed.

The price of the vaccine has risen accordingly. In 1982, it cost just 11 cents a dose. Last year, Lederle, which has about one-half of the DPT market, charged \$4.29 a dose and Connaught, the only other company that sells the vaccine in the United States, charged \$4 a dose to the private sector and \$3.01 to the CDC.

On 20 May, Lederle announced that it will be insuring itself and raising its prices to \$11.40 per dose when its insurance expires on 30 June. The price includes an \$8 per dose insurance reserve. Since the company sells about 10 million doses of the vaccine a year, it is clearly preparing for substantial damage awards. Connaught announced on 27 May that it is remaining with its insurance company but is raising its price to the private sector to \$10.38 a dose. Its price to the CDC will remain the same.

By all accounts, the DPT lawsuits can be extremely costly. Hinman observes that the

true price of this litigation is not yet established because, so far, very few suits have gone to trial and when out-of-court agreements were reached, the parties remained silent on whether there were awards and, if so, how much was awarded. Moreover, according to Hinman, the number of suits actually settled so far is quite small—in the neighborhood of 20.

Attorney Anthony Colantoni, of the Chicago firm McDowell and Colantoni which handles most of the plaintiffs' suits, says he knows of only one DPT lawsuit that failed. Plaintiffs typically are awarded \$1 million or more, according to Colantoni, who is handling nearly 200 DPT suits. Not all of these suits are against Lederle or Connaught. They include suits against companies such as Wyeth and Parke-Davis that have gotten out of the business of selling DPT vaccines. Nonetheless, 100 lawsuits were filed against Lederle in 1985 alone.

Colantoni points out, however, that the large awards reflect the fact that the children typically have very serious injuries. A Cleveland boy, Tyler White, for example, was awarded \$2.1 million in March, but he was left profoundly retarded following his DPT injection. He now has the mentality of a 6-month-old and no prospects for any improvement, according to Colantoni.

In the absence of legislation to compensate vaccine victims and in the absence of a safer vaccine, the current situation is entirely predictable. Whether the price increases will spur Congress to act on vaccine compensation remains to be seen. ■ GINA KOLATA

Space Commission Sets Goals for 21st Century

After a year of study, the National Commission on Space has announced its recommendations for a phased program of space development over the next 50 years. The report, released on 23 May, envisions a new series of launch vehicles capable of lifting passengers and cargo into orbit at less than one tenth the launch cost of the space shuttle; interplanetary factories using raw materials mined from the moon and the asteroids; a series of service-and-supply "spaceports" in orbit around the earth, the moon, and Mars; and permanent human outposts on the moon and on Mars by the early decades of the 21st century.

"In the wake of the Challenger accident, this is a good time to pause and thoughtfully reassess where we should be going in space," says commission chairman Thomas O. Paine, a former administrator of the Nation-

al Aeronautics and Space Administration (NASA). "The commission is *not* recommending an Apollo-type crash program to go to Mars. We lay out a logical, non-crash program . . . The report is not a detailed blueprint, but a vision of what the country could accomplish in the coming decades if we decide to do so."

The 15-member commission was appointed by President Reagan last year at the request of Congress and was given the task of defining an agenda for the civilian space program covering the 50-year period beginning in 1995. The commission identified three national goals for the space program: science, including space astronomy, planetary exploration, and a detailed global study of the planet Earth; the human settlement of the solar system, supported by the exploitation of extraterrestrial materials on the moon and asteroids; and the fostering of space commerce, especially in launch services and zero-gravity materials processing.

To accomplish these three goals, the commission urges a national commitment to two other supporting goals. The first is an expanded program of research into basic space technologies such as advanced transportation systems, power systems, and life support. The second is the creation of a system of low-cost launch vehicles and space stations that will enable operations in space to be much less expensive than they are now. "It is especially important that the cost be dramatically reduced for free enterprise to flourish with commercialization of space operations," says the report. With a systematic program of development, the commission is confident that advanced vehicles could reduce the launch costs to below \$200 per pound by the year 2000.

One item in the report that will be of particular interest to the scientific community is the commission's emphasis on intelligent robots in addition to manned spaceflight. Such robots might explore the Martian surface prior to a manned landing, for example. Also intriguing is the commission's recommendation for a new administrative entity, the National Space Laboratory, which would be responsible for planning space-based laboratory facilities. In the same vein, the commission also recommends that NASA's funding for research in space laboratories be supplemented by funding in related areas from the National Science Foundation, the Energy Department, and the National Institutes of Health. All would be coordinated by the National Space Laboratory.

In estimating the financial resources available for the space program, the commission assumed that about 75% of the total program costs would be borne by the taxpayer,

and the rest by the private sector and international partners. Furthermore, the commission assumed that the U.S. gross national product would grow an average of 2.4% per year, and that NASA's budget would grow proportionately. In the early decades of the 21st century, the agency would thus be spending roughly \$20 billion to \$30 billion per year.

It remains to be seen what the White House and Congress will make of all this. In constant 1986 dollars, NASA's budget has been static at roughly \$7.3 billion since 1976. And while the agency may get new money to replace the Challenger, its baseline budget is unlikely to rise until the federal deficit crisis is resolved. ■

M. MITCHELL WALDROP

Field Test of Altered Microbe Still in Limbo . . .

"It's really very perplexing," says Steven Lindow, a scientist at the University of California at Berkeley who wants to field test microbes altered to curtail frost formation on plants. Three weeks ago, Lindow, after waiting nearly 2 years, won federal approval to conduct the experiment on potato plants, but he still cannot proceed because local opposition is mounting.

As a result of local public sentiment, the university has temporarily withdrawn its permission to proceed with the experiment. And, on 2 June, the board of supervisors of Modoc County where one of the test sites is located, passed a resolution requesting that the test be delayed.

Lindow is frustrated and surprised that the test has generated so much anxiety among residents of Tulelake, California, a rural town located a mile from the Oregon border. The experiment has been judged to be virtually harmless by expert advisers to the the National Institutes of Health and the Environmental Protection Agency, and agency scientists themselves. While the test proposal was under federal review, Lindow and the university met with local officials and growers to explain the experiment and found little resistance. They redoubled their efforts after protests erupted in Monterey County last January over a similar experiment planned by a biotechnology company, Advanced Genetic Sciences of Oakland.

Protests among Tulelake citizens were sparked after a Monterey County resident recently spoke against the test at a Tulelake Grange meeting. His appearance was unknown to Lindow, so "there was no chance for rebuttal," Lindow said in a telephone interview. He and the university are now

trying to repair the damage. In preparation for the meeting of the Modoc County board of supervisors, the university put together information packets about the test to educate residents. But commercial potato growers in Tulelake, who generally have supported the experiment, are now getting nervous that adverse publicity about the test will prompt a boycott of their crops. "It's a very emotional situation," he said. "It's basically a fear of the unknown."

Lindow said that the university on 20 May "unexpectedly" withdrew his authorization to conduct the test at the school's Tulelake experiment station, even though he was still waiting to proceed with test. A university spokeswoman said that it hopes to announce a date "in the next week" when the test can go forward.

The experiment is only a small part of Lindow's total research. Asked if the test has been worth pursuing, he said, "It's the stupidest thing I've ever done. I wouldn't do it again. I wouldn't recommend it to anyone else—not until people are better educated in science." ■ MARJORIE SUN

. . . While First Outdoor Test of Engineered Plant Begins

The first outdoor test of plants altered by recombinant DNA methods began on 30 May when Agracetis, a Wisconsin biotechnology company, planted 200 tobacco seedlings that have been modified to resist crown gall disease. The test represents a small but significant step for agricultural biotechnology.

The purpose of the experiment is to analyze whether the genetic modification changes the plants' yield in an outdoor environment. Agracetis, which is jointly owned by Cetus Corporation and W.R. Grace & Company, used a special vector, a Ti plasmid, to transfer the disease-resistance genes. The vector system potentially could be used to make food crops resistant to specific diseases.

Agracetis is testing the tobacco plants only as a model system and has no interest in commercializing them, said Robert Fildes, president of Agracetis and chief executive officer of Cetus in Emeryville, California. The experiment is being conducted in Midletown, near Madison, on a 2000 square foot plot.

The test proposal was approved by the federal government last November after the National Institutes of Health and the U.S. Department of Agriculture reviewed

the proposal. The Wisconsin Department of Natural Resources also approved the test.

The company has been waiting nearly 2 years to conduct the test and it conferred with local officials prior to going ahead. "We worked real hard to make sure everybody was aware of what we were up to," said Fildes. But as a precaution, the company is not disclosing the exact location of the test site to prevent vandalism. ■

MARJORIE SUN

Ariane Failure Hits Europe's Space Efforts

Europe's space ambitions received a major setback last week when an Ariane rocket which was to have launched a telecommunications satellite for the international consortium Intelsat had to be destroyed a few minutes after lift-off, following an ignition failure in the rocket's third stage.

All further Ariane launches have been suspended until a report on the accident has been prepared by a special commission which was immediately set up by the chairman of Arianespace, Frederic d'Allest. Arianespace is the company that has been set up to take commercial responsibility for all Ariane launches.

The rocket's failure puts a temporary hold on Arianespace's efforts to capitalize on the delays to the U.S. launcher program caused by the shuttle disaster in January. In recent weeks, Arianespace had announced several new contracts with customers who had previously been considering using the shuttle.

It was the fourth failure in 18 launches for Ariane, and the second in less than 9 months. Two factors are particularly disturbing to European space engineers. The first is that it was the first launch of a new, more powerful version of the rocket, known as Ariane 2.

The second factor was that three out of the four failures have occurred as a result of malfunctioning in the ignition system for the rocket's third stage.

Arianespace officials in Paris have predicted that the launch failure will lead to a delay of at least 1 month in the current schedule for future flights. The delay could be considerably longer if it is felt that a major redesign of the fuel injection system for the third stage is required.

Last week's launch failures also means that, following closely on the failures of the U.S. space shuttles and the Titan and Delta launchers, the West currently has no commercial launchers available for placing large payloads into earth orbit. ■

DAVID DICKSON