

Rachel's Environment & Health News

#322 - New Perspectives On Toxics -- Part 1: America Learns About Teratogens

January 26, 1993

In 1954, enterprising German chemists created a new drug, which they named thalidomide.[1] It seemed to be an ideal sleeping pill and tranquilizer, and after three years of animal tests thalidomide was judged so safe that it was approved for over-the-counter (non-prescription) sale throughout Germany. By 1960, thalidomide was Germany's most popular sleeping pill and tranquilizer. It was a huge financial success, marketed under 50 different trade names in 24 countries.

In 1960 the Merrell pharmaceutical company of Cincinnati applied to the U.S. Food and Drug Administration (FDA) for permission to market thalidomide in the U.S. The application was assigned to FDA staff member Frances O. Kelsey who had 60 days to consider the application.

To the Merrell Company's distress, Dr. Kelsey asked for more data; she was concerned that thalidomide acted differently in animals than it did in humans (it wasn't a sedative in animals). The Merrell Company sent officials to Washington to complain that Dr. Kelsey was holding up progress, but FDA officials held firm.

During this time a single report appeared in a British medical journal, indicating that some long-time users of thalidomide had developed nerve damage in their hands and feet. The Merrell company proposed to put a warning label on the package, but Dr. Kelsey replied that Merrell would need to conduct studies to show that thalidomide could be safely taken by pregnant women without harming the fetus. Merrell officials were appalled that this "stubborn bureaucrat" could derail their plans for marketing a sure-fire best-seller. However Dr. Kelsey held firm, and so did her supervisors at FDA.

Long before Merrell could complete its tests, news filtered across the Atlantic from Germany of an outbreak of phocomelia (literally "seal limbs")--a terrible deformity in which babies are born with tiny flipper-like stumps instead of arms and hands. In November, 1961, Dr. Widuking Lenz in Germany and Dr. W. G. McBride in Australia, almost simultaneously, observed that the mothers of several babies with phocomelia had one thing in common--they had taken thalidomide in the first 20 to 40 days of pregnancy.

In September, 1962, the extent of the disaster in West Germany was officially confirmed. Since 1957, when the pill was first approved for over-the-counter sales, thalidomide has caused 10,000 cases of birth malformations in West Germany. Nearly a thousand other cases were reported in England. So far as we know, no one has ever tallied the damage in the 22 other countries where thalidomide was sold--in western Europe and Japan, and throughout South America.

Interestingly enough, the thalidomide story was told in several places--in *SCIENCE* magazine (5/25/62), and in the *NEW YORK TIMES* (4/12/62)-- back on page 37--but it drew no real attention until Morton Mintz of the *WASHINGTON POST* told the story on page 1 (7/15/62) about Dr. Kelsey, who had single-handedly held firm against great pressure and abuse, thus averting an American thalidomide tragedy. (Seventeen American babies were born with phocomelia because, as was allowed at the time, Merrell gave free samples to physicians as soon as the company applied to FDA for permission to sell the drug.) The heroism of Dr. Kelsey caught the public imagination, and then the thalidomide story spread rapidly. President Kennedy eventually awarded Dr. Kelsey a medal for Distinguished Civilian Service.

Congress responded to thalidomide by passing the Kefauver-Harris drug law, which the President signed in October, 1962. This law, for the first time, gave FDA the power to require specific procedures for testing new drugs for safety and effectiveness.

But a much broader change began to occur as a result of the thalidomide disaster. Up until this time, some Americans had been concerned about cancer from chemicals, but thalidomide brought home the dangers of teratogens and mutagens. Teratogens cause

birth defects and mutagens cause inheritable genetic changes.

As a result, Americans in general became a little less eager to try the latest drug for every new ailment. And they gained new respect for the great damage a small amount of a chemical might do.

The next developments in our consciousness of chemicals occurred in the workplace. Workers have always been the people exposed first to new chemicals, and exposed most heavily. Up until 1970, when Congress passed the Occupational Safety and Health Act, workers were not protected in any systematic way from chemicals. There were no federal standards for exposure and no legal protections except a patchwork quilt of conflicting state statutes. Naturally, management had some appreciation of acute toxic effects from chemicals (sick workers can't be productive, and they might sue), but the only long-term consequence that anyone talked about was cancer. Although the systematic medical literature on occupational health reaches back to the year 1700, concern about teratogens and mutagens is almost brand new. Even as recently as 1969, the "standard" work on occupational safety and health, Donald Hunter's *DISEASES OF OCCUPATIONS*, in its fourth edition contained no references to either teratogens or mutagens.

However, the thalidomide disaster prompted a great deal of research on reproductive health and chemicals, and by the mid-1970s articles began to appear in the medical literature linking chemical exposures of both men and women to miscarriages, infertility, and other reproductive disorders.[2]

However, as knowledge of teratogens and mutagens developed, measures to protect workers took a peculiar turn.

Although the early studies clearly showed that chemical exposures of both women AND MEN could damage offspring, corporate management tended to ignore the evidence about male exposures and developed policies aimed only at "protection" of women.

The issue came to the forefront in the late 1970s when it became widely publicized that the American Cyanamid Company had established a policy barring all fertile women from numerous high-paying jobs at its Willow Island, West Virginia, plant, claiming the prohibition was necessary to avoid the possibility of birth defects in the offspring of exposed workers. The American Cyanamid case was particularly troublesome because five women workers at the plant "voluntarily" underwent surgical sterilization so they could keep their jobs.[3] Despite the ugly cast of these measures to "protect" women, such policies spread rapidly throughout American industry. Rather than clean up the workplace, management found it expedient to exclude female workers on the specious grounds that their reproductive systems were sensitive to chemicals, whereas men's were not. (As a sidelight, it is interesting to recall that the "right to know" movement has its origins in this same period; rather than clean up work places, authorities began to agree to allow workers to learn the names and some of the characteristics of the chemicals they were being exposed to.)

Throughout the 1980s, the "protection" issue continued to fester. For many women, it was a simple matter of rights; they did not want to be told they had to choose between having a child and having a job.

Federal courts decided half a dozen cases involving "fetal protection" policies (cases involving Olin Corp., General Motors, B.F. Goodrich, and several hospitals). In no instance was a company's discriminatory policy struck down. The best-known case was that of Johnson Controls, the nation's largest manufacturer of automotive batteries. A coalition of labor and women's rights activists challenged Johnson's policy of excluding women from jobs involving exposure to lead. (To keep her job on the production line at any Johnson Controls' battery factory, a woman had to offer medical proof that she was sterile.)

In October, 1989, a panel of judges on the federal Court of Appeals for the 7th Circuit in Chicago ruled that Johnson had the right to

exclude fertile women from jobs involving exposure to lead, even women who said they had no intention of getting pregnant. One judge on the 7th Circuit bench, who dissented in the Johnson Controls case, estimated that 15 to 20 million women would be excluded from high-paying jobs by the majority's decision.[4]

However, a broad coalition of labor and women's rights organizations pursued the case into the U.S. Supreme Court and on March 20, 1991, the court ruled unanimously that employers had no right (under the Civil Rights Act of 1964) to discriminate against women even to "protect" them or their fetuses.[5]

With that argument settled, scientists and medical researchers have begun to recognize, and to confirm, what the older literature had showed 20 years ago.[6] They are finding that toxic chemicals can cause men to father defective children. Yes, toxic sperm, a subject we will examine next week.

--Peter Montague

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[1] Edward W. Lawless, *TECHNOLOGY AND SOCIAL SHOCK* (New Brunswick, N.J.: Rutgers University Press, 1977), pgs. 140-[147.]147.

[2] For example, I. V. Sanotskii, "Aspects of the Toxicology of Chloroprene: Immediate and Long-Term Effects," *ENVIRONMENTAL HEALTH PERSPECTIVES* Vol. 17 (1976), pgs. 85-93. And: Peter F. Infante and others, "Genetic Risks of Vinyl Chloride," *THE LANCET* (April 3, 1976), pgs. 734-735.

[3] Joan E. Bertin, "People Protection Not 'Fetal Protection,'" *NEW SOLUTIONS* (Summer 1991), pgs. 5-9.

[4] William E. Schmidt, "Risk to Fetus Ruled as Barring Women from Jobs," *NEW YORK TIMES* October 3, 1989, pg. A16.

[5] Linda Greenhouse, "Court Backs Right of Women to Jobs With Health Risks," *NEW YORK TIMES* March 21, 1991, pgs. 1, B12.

[6] Sandra Blakeslee, "Research on Birth Defects Turns to Flaws in Sperm," *NEW YORK TIMES* Jan. 1, 1991, pgs. 1, 36.

Descriptor terms: birth defects; reproductive hazards; thalidomide; merrell pharmaceutical co; fda; germany; great britain; cancer; carcinogens; teratogens; mutagens; occupational safety and health; workers; health; exposure; hazardous materials; miscarriages; infertility; american cyanamid; fetal protection policies; johnson controls;