THE FIRST STONE

TAKE A POWDER

By Joel Bleifuss

Women who frequently use talcum powder on their genital area significantly increase their risk of getting cancer. Yet despite clear evidence of an association between the mineral talc and ovarian cancer, both the U.S. Food and Drug Administration and the cosmetic industry's main trade group refuse to acknowledge these findings and to regulate the use of talc.

A 1992 study published in the medical journal *Obstetrics & Gynecology* examined the history of talc use in 235 white women with ovarian cancer and 239 white women without the disease in the Boston metropolitan area. The research team, led by Bernard Harlow of Harvard Medical School's Obstetrics and Gynecology Epidemiology Center, found that women who regularly applied talc to their genital area increased their risk of contracting ovarian cancer threefold.

In the study, 49 percent of the women with ovarian cancer and 39 percent of those without the disease reported some level of genital exposure to talc. The researchers found that the "most frequent method of talc exposure was use as a dusting powder directly to the perineum." Further, they noted that "brand or generic 'baby powder' was used most frequently and was the category associated with a statistically significant risk of ovarian cancer." Fourteen percent of the women with ovarian cancer in the study had applied talc to their perineum an estimated 10,000 or more times during the years when they were ovulating with an intact genital tract—compared to 7 percent of women without the disease.

The researchers warned that "given the poor prognosis for ovarian cancer, any potentially harmful exposures [to talc] should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit."

The study concluded that about 10 percent of all ovarian cancer cases may be attributed to the frequent use of talc. Ovarian cancer, the incidence of which is on the rise, is the fourth deadliest cancer among women, killing about 14,000 American women each year.

Talc, a mineral related to asbestos, has been an object of scientific scrutiny for decades. As early as 1968, scientists examining cosmetic talcum products discovered that 22 of those they analyzed had, on average, a mineral fiber content of 19 percent. In 1971, researchers discovered talc particles deeply embedded in 75 percent of ovarian tumors studied.

Such evidence led the FDA in 1973 to draft a resolution that would have limited the amount of asbestos-like fibers in cosmetic-grade talc to less than 0.1 percent. But no ruling was ever made, and the cosmetics industry was left to police itself and rid baby powder and other talc products of asbestos-like fibers.

To their credit, cosmetic manufacturers appear to have reduced the volume of asbestos-like fibers found in the 77,000 metric tons of cosmetic-grade talc that the U.S. cosmetics industry uses each year—at least that's what the industry and FDA claim. But even without asbestos-like fibers, talc is a matter of concern.

In 1993, the National Toxicology Program conducted

Carcinogens in shampoos and lotions

The FDA is not doing enough to ensure that many foods and cosmetics are free of carcinogenic nitrosamines, according to William Lijinsky, the former director of the Chemical Carcinogenesis Program at the National Cancer Institute's Frederick Cancer Research and Development Center. The fewer tests that are done, the fewer problems there will be to find. "It is very logical," he explains. "If you don't look, you don't find."

FDA cosmetics researcher Donald Havery describes Lijinsky, who is now retired, as the scientist who has "done more work than anybody for testing nitrosamines for carcinogenicity." Nitrosamines are potent carcinogens that have been frequently found to contaminate shampoos and lotions (see "The First Stone," February 17).

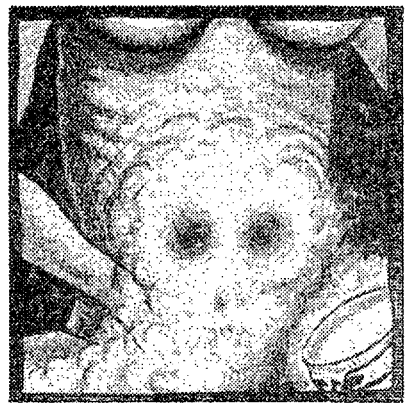
Lijinsky says he was particularly concerned to hear FDA Commissioner David Kessler, in a November 1995 radio interview, dismiss "as myth from long ago" the role of nitrites—precursors to nitrosamines—in promoting human cancer. Lijinsky says Kessler failed to realize "that the nitrosamines are the most potent carcinogens we know and active at extremely low concentrations in animals." In a letter he wrote to Kessler in response to the radio interview, Lijinsky pointed out that nitrosamines are so carcinogenic that they "give rise to tumors within the short lifespan of a rat." And, he added, "There is no doubt that such reactions occur in humans."

Lijinsky says the level of nitrites allowed in food should be further limited, and that the FDA should closely monitor and control the level of nitrosamines—or other nitrosamine precursors, such as DEA—in cosmetic ingredients. By itself, DEA is harmless, but when combined with nitrites, it forms the

an animal study of "non-asbestiform talc" (talc which does not contain asbestos-like fibers) and concluded that when inhaled, it was carcinogenic to rats. The study was requested by the National Institute of Occupational Safety and Health, which has been a more rigorous protector of public health than the FDA.

So is talc harmful?

It's important to remember that the Food, Drug and Cosmetics Act regulates cosmetics differently from food, says Arthur Whitmore, the FDA's Cosmetic Technology Branch spokesman. In the case of cosmetics, he adds, "The burden of proof is on the FDA to prove that a product is harmful under condition of use." Don Havery, an FDA cosmetics researcher, puts it this way: "You don't see a lot of regulatory action because it is very difficult to prove harm."



But what is considered proof? According to the Cosmetic Toiletry and Fragrance Association, the trade group of the $20-billion-a-year cosmetics industry, "no scientific study has ever demonstrated that talc causes ovarian cancer." The CTFA official position paper on talc maintains that "the latest toxicologic and epidemiologic studies conducted on talc" were reviewed at a 1994 workshop entitled "Talc: Consumer Uses and Health Perspectives," co-sponsored by the FDA and the International Society of Regulatory Toxicology and Pharmacology. According to the CTFA, workshop participants concluded that "when taken together, the results of these studies [linking talc use and ovarian cancer] are insufficient to demonstrate any real association."

That conclusion, however, contradicts the assessment of Bernard Harlow, whom workshop organizers had asked to review the latest epidemiological studies examining potential links between talc use and ovarian cancer. Harlow presented his review at the workshop and later published it in the journal *Regulatory Toxicology and Pharmacology*. The review's data show that four of eight studies since 1982 "implicated use of body powders" with increased ovarian cancer risks of 50 percent or more. He concludes that from an epidemiological point of view, it is "plausible" that any genital application of talc increases a woman's risk of ovarian cancer by as much as 80 percent.

"The studies that are out there suggest there is a risk," says Harlow. Asked whether his family uses talc products, he replies that they never used talc-based baby powder on their daughter. "My wife certainly doesn't use any talcum powder in her genital area," he says. "I certainly wouldn't recommend it."

So why does the CTFA cite the workshop to refute the link between talc and ovarian cancer? And why has the FDA not taken action, since ample evidence points to such a link? Despite repeated queries, the FDA failed to respond to this question by press time.

It's hard not to conclude that the FDA has no interest in finding proof. For their part, researchers know what other avenues need to be explored. Harlow ends his review of the talc-ovarian cancer connection by saying "the greatest need is to confirm or deny the reports of talc embedded in human ovarian tissue and the report of easy transportation of particles through the female reproductive tract."

The Chicago-based Cancer Prevention Coalition has petitioned the FDA to require that all cosmetic talcum-powder products carry a warning such as: "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." The FDA could also follow the example of the European Union, which stipulates that talcum powder, like Johnson & Johnson baby powder, is not to be used in products for children under 3 years old.

potent carcinogen NDELA, which is the nitrosamine most commonly found in cosmetics.

In 1979, then FDA Commissioner Donald Kennedy threatened regulatory action if the cosmetics industry did not "take immediate measures to eliminate, to the extent possible, NDELA and any other N-nitrosamines from cosmetic products." Since then, the FDA has monitored the level of nitrosamines found in cosmetic products. But from 1985 to 1996, the FDA analyzed only 47 cosmetic products for NDELA, 23 of which were found to be contaminated with the nitrosamine. Havery says that his office has only one chemist and "he does work other than nitrosamines."

Lijinsky has some sympathy for the FDA's surveillance program. "NDELA, the principal nitrosamine in cosmetics, is absorbed through the skin particularly in an oily solution [like lotion], and it is quite a potent carcinogen," he says. "But one of the problems is that it is difficult and expensive to measure, and there are thousands of products that have to be monitored, so I can understand why they don't do it."

One way to avoid the problem of monitoring all these cosmetic products would be to regulate the amount of DEA allowed in cosmetics. The European Union restricts DEA contamination to 1 percent of any cosmetic ingredient. DEA is currently found in much higher levels in products in the United States. According to Havery, an unpublished FDA study of 20 cosmetic raw ingredients found DEA in concentrations of up to 13 percent. However, only two of the FDA's samples exceeded the manufacturer's specifications—based on limits provided by the Cosmetic, Toiletry and Fragrance Association, an industry group. The CTFA advises its members that DEA levels should not exceed 5 percent of a final cosmetic product—significantly higher than the European level. —J.B.

HEALTH CARE

The Wal-Mart of hospitals

Columbia, America's largest hospital chain, gobbles up nonprofits, slashes basic services and raises prices.

By Sean Cahill

As the number of uninsured Americans grows, the health care industry is raking in record profits. That money flows into the pockets of a handful of corporate giants now asserting dominance over the field. Every three days, there is another hospital merger or acquisition—often of a nonprofit gobbled up by a for-profit. According to Public Citizen, 447 community hospitals were objects of mergers or acquisitions in 1995, and 58 nonprofit hospitals converted to for-profit status in that year alone.

The exigencies of managed care are driving the hospital-merger mania. Hospitals merge to increase size and market power, and thus cut costs, enhance their ability to negotiate with insurers and better compete with health maintenance organizations. According to *Modern Healthcare*, the amount of money hospitals spent on care for the poor dropped in 1994 for the first time in more than a decade, even as profits jumped 17.3 percent to a record high of $13.8 billion.

For-profits currently comprise 15 percent of the nation's hospitals, and a 1996 Coopers & Lybrand study estimates that for-profits will own one in four hospitals by the turn of the century. Columbia/HCA, the nation's largest for-profit hospital chain, is leading the charge. Columbia owns 10 percent of the nation's hospitals, including about one-third of Florida's hospitals and 80 percent of Utah's hospital beds. This $20 billion giant owns a total of 350 hospitals and 133 outpatient surgery centers in 38 states. Columbia's game plan is to vertically integrate in order to provide "one-stop shopping"—owning everything from the hospital to the insurance company, the home health care provider and the local pharmacy.

The company says it brings private-sector efficiency to flabby nonprofits, cutting health care costs while improving patient care. A growing legion of opponents, however, sees things differently. They argue that Columbia and other for-profit hospital chains are buying up the country's health care infrastructure at far less than these institutions are worth, creating quasi-monopolies. They then slash basic services like trauma care—which too many uninsured patients use, making it unprofitable—and jack up the price of services across the board to boost profits. For-profit hospital executives and shareholders are making out like bandits. Columbia founder and Vice Chair Thomas Frist made it onto the 1996 *Forbes* list of the 400 richest Americans, amassing a net worth of $1.1 billion. Meanwhile, consumers, the uninsured and the employers who pay for higher health care costs end up footing the bill.

Gobbling up nonprofit institutions like Pac-Man, Columbia has merged with or acquired more than 340 hospitals since 1987. In 1995 alone, the company negotiated 27 deals to purchase nearly three dozen nonprofit hospitals. The chain pays bargain-basement prices for community-built institutions that have been subsidized for decades by taxpayers. Unlike for-profits, which are owned by and accountable to their shareholders, nonprofits are usually owned by a university, religious institution or municipal government, and are incorporated as charitable trusts. The bylaws of these nonprofit hospitals usually empower the board of directors to sell the hospital, sometimes by a simple majority. In recent years, many have sold due to an increasing inability to compete in the managed-care marketplace.

Despite the nonprofits' community mission, institutionalized mechanisms rarely exist for community review of the sale decision. In nearly all cases, the only party with legal standing to intervene in a transfer or sale of charitable assets is the state attorney general. Furthermore, because the sales