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Fighting Independent Risk Assessment of Talc and Glyphosate: Whose Benefit Is It Anyway?

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 See also Rosner et al., p. 969; Michaels, p. 975; Samet, p. 976; Vineis, p. 978; Rodenberg, p. 980; and Singla et al., p. 982.

The vast majority of Americans trust that science is an essential component of modern decision-making and should fuel policy-making. Despite vociferous opposition to the scientific evidence on the safety of vaccines today, 80% to 90% of US parents vaccinate their children, and only 13% of Americans said in 2016 that they did not fully believe vaccines were safe (am.ajph.link/PEW_Vaccines2019). It is, therefore, not an issue of political preference, race, religion, or any other social divide. Scientific evidence is one of the rare issues on which people may agree even though they widely differ in their personal beliefs. But science can play its role only if it is produced independently of these other forms of interest, be they of a financial, career promotion, political, religious, racial/ethnic, or any other nature. The articles in this issue illustrating attempts to discredit independent scientific assessment for the sake of corporate interests made me ask a question I had never asked myself before: is fighting independent risk assessment really in corporations' interests?

BABY POWDER

Consider how the trade association of cosmetic talcum powder

manufacturers maneuvered the Food and Drug Administration (FDA) to authorize the sale of talcum powder containing asbestos. It was able to impose a test screening for “nondetected” levels of asbestos, which would leave up to 1% of asbestos in the talc, that is 10 times more asbestos than the 0.1% the FDA requested. Commercial talcum powder, such as baby powder, is a mineral product extracted from rock ore dug from mines, originally in Italy and later in Vermont. It is a mix of hydrated magnesium silicate with other minerals, including asbestos fibers. A Reuters investigation (am.ajph.link/Reuters_JandJ2018) revealed that Johnson & Johnson, the company that produces it, knew for a long time that its baby powder contained fibers but disputed scientists' charges that it was a health risk for its clients. As shown by Rosner et al. (p. 969), scientists had warned that the quantity of asbestos undetectable using the manufacturer's radiographic test amounted to billions of asbestos fibers per grams of talc. Asbestos is a known carcinogen. Now ovarian cancers are being diagnosed among women who used Johnson & Johnson's talc (“baby powder”), and courts are ruling in favor of the women.

Was it really in the industry's interest to impose its own risk

assessment? Let's explore Rodenberg's (p. 980) idea that the industry should see independent risk assessment as an ally rather than a foe because it is in its interest to avoid natural and humanitarian catastrophes. Johnson & Johnson and its advisors underestimated the risk that independent scientists had correctly assessed. I have estimated the cost and benefit of this failure for Johnson & Johnson assuming a purely capitalistic, conscienceless, amoral perspective in which the aim of the company is to maximize its profit, ignoring the entailed human cost.

The lawsuits against Johnson & Johnson already cost the company \$4.69 billion, which went to 22 women who blamed their ovarian cancer on asbestos in the company's baby powder and other talc products. Coming next are thousands of other plaintiffs, including women with ovarian cancer, suing the company, arguing that the talc is responsible for their cancer. The litigation cost can be expected to grow rapidly in the coming years. In addition, Johnson & Johnson invested resources to develop its

insensitive screening test for the presence of asbestos in the talc. The company's stock dropped, wiping out additional billions in Johnson & Johnson's market value. Perhaps most important for the long-term profitability and sustainability of the company, the tragedy has forever stained the heretofore beneficent public image of the “family-friendly” company producing “baby shampoo” and “baby powder,” whose former owner, Robert Wood Johnson II, endowed the highly respected and independent eponymous foundation with more than 10 million shares of the company's stock.

Trust is broken and sales may drop. In terms of profits, grossly, extrapolating the 2017 revenue data of Johnson & Johnson provided by Reuters (am.ajph.link/Reuters_JandJ2018), if the company made \$420 million per year of revenue from the baby powder over 50 years, this amounts to \$21 billion (= 420 × 50), or 5 per thousand of the overall revenue of \$4 trillion (i.e., declared \$80 billion for 2018 × 50 years) the company could have made during this period. There may have been additional indirect benefits Johnson & Johnson was reaping from the talcum powder, but it is difficult to imagine, even adopting a cynical capitalistic perspective, that the 50 years of extra profit Johnson & Johnson made by refusing to implement a more rigorous purification of the talc or

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replacement of the talc by another substance outweighed the tremendous cost.

BAYER-MONSANTO GLYPHOSATE

To defend what they perceive as in their best interests, some corporations not only pressure governmental agencies, they fight them. Samet (p. 976) describes how Monsanto has moved extremely aggressively against the science, the unpaid expert volunteers, and institutions such as the International Agency for Research on Cancer (IARC), which tried to share the result of their independent assessment of glyphosate (Roundup) as a possible carcinogen. These actions imperil the existence of the peer review processes but maybe the survival of Bayer (which bought Monsanto) too.

As in the case of Johnson & Johnson's talc, the dramatic consequences of neglecting the independent risk assessment of

glyphosate are unfolding. As I write, Bayer lost a third trial against a French farmer, Paul François, who suffers from neurologic problems that the courts have causally linked to glyphosate, and a California jury awarded \$2.055 billion to a couple for cancers caused by the weedkiller. There are 11 200 more plaintiffs lined up. Bayer's stocks have lost 40% since 2018 and keep going down, and the image most people have of Bayer, as the company that produces the wonder drug aspirin, may be forever stained. This may have been avoided had Monsanto informed the public that independent science established that glyphosate was "genotoxic" and "probably" caused cancers in humans.

PUBLIC HEALTH CONSCIENCE

The independent assessment of risk associated with industrial products is, as Vineis (p. 978) reminds us, part of the checks and balances that are indispensable in a

democratic society. The industry cannot be expected to impartially assess the potential toxicity of its own products. Independent risk assessment requires specific procedures and skills for the conclusions arising from reviewing and summarizing a large body of evidence to be transparent and useful for policy decisions. IARC monographs are an ingenious way to do exactly that. The conclusions of their unpaid expert volunteers cannot be replaced by reviews from scientists paid by the industry.

Independent risk assessment has a cost. To play their role as independent checks, governmental and international agencies need resources. Michaels (p. 975), former assistant secretary of labor for the Occupational Safety and Health Administration, stresses that lack of resources handcuffs many public health agencies. In the case of the asbestos-related risk from talc, the FDA's lack of money and manpower may explain why it could not challenge the industry's obviously inadequate risk assessment procedures by generating its own,

polarized microscopy asbestos screening test. The underresourced Federal Aviation Administration's missed assessment of the safety of the Boeing 737 MAX is another case in point.

Some corporations do not hesitate to undermine the legitimacy and credibility of the institutions, such as the FDA, the surgeon general, the Environmental Protection Agency, the Centers for Disease Control and Prevention, or the IARC, whose missions are to produce or summarize the science to protect all of us from harmful, toxic products, behaviors, or policies. But the cases of talc and glyphosate speak for themselves: it was in Johnson & Johnson's and Monsanto's best interest to support and respect the independent, conscientious scientific risk assessment. The converse is not true: the public could not rely on the corporate industry's scientists or on the industry itself to have a public health conscience. **AJPH**

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