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Controversial Chemical Poses Disclosure Challenge for Colgate-Palmolive



by Tom Stabile

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A feisty debate over the safety of a widely used chemical has put **Colgate-Palmolive** at the center of a case study in product disclosure and corporate responsibility - one that may ultimately help outline how companies wading through a murky regulatory review and unsettled science should attend to their stakeholders and customers.

The current squeeze on Colgate stems from a U.S. Food and Drug Administration decision this year to train its microscopes more closely on triclosan, a chemical with antibacterial properties that in recent decades has been added to scores of products, but now is under new scrutiny because of studies that suggest it may harm both human health and the environment. And while the FDA conducts its review – and critics of triclosan mount their arguments to curtail its use by consumers – Colgate and other product manufacturers have to decide what they can and should say to the marketplace, not to mention when and how to convey it.

The hurdle the company faces is clear: a core ingredient of its top-selling **Colgate Total** toothpaste is suddenly the heart of a public health tempest, but regulators have neither banned the chemical nor deemed it unsafe. There is no well-tested playbook for the scenario, says **David Nash**, partner at McMahan DeGulis, an environmental law firm based in Cleveland.

“The dilemma becomes, what kind of legal, moral, or socially responsible duty do they have to stakeholders to go beyond where the regulatory agency has already gone?” he asks. “In this fast-moving field, I would be hard-pressed to say [there is a] consensus on best practices.”

It complicates matters for Colgate that few products have gotten more mileage out of triclosan than Colgate Total, which won special FDA approval in 1997 for its use of the chemical in a patented formula to prevent gingivitis, a common form of gum disease. In short order, Colgate Total vaulted above competitors to become the top-selling product, and today it remains a big contributor to Colgate’s worldwide 44.4% share of the global toothpaste market and its 35.6% slice of the U.S. market, **according to company filings this year**. At the beginning of last year, **Colgate announced** that among its toothpaste varieties, the Colgate Total brand by itself had 16% of the overall market in North America.

Another thorny issue for Colgate is that the **FDA is heightening attention on triclosan (PDF)** at the same time it serves as the first line of defense against critics. That's because on the one hand, the FDA is teaming up with other federal regulators, particularly the **Environmental Protection Agency (PDF)**, to sponsor new research on triclosan's safety. But on the other, the **FDA has issued a statement** that "triclosan is not currently known to be hazardous to humans" and that the agency "does not have sufficient safety evidence to recommend changing consumer use of products that contain triclosan at this time" – and won't have its first answers until spring 2011.

That leaves product makers with decisions that perhaps they would not have faced even 10 years ago, when corporate social responsibility factored far less in the strategic thinking at most companies. Should a company proactively inform its customers that a key ingredient of its product is facing questions? Should it amend its marketing? Should it play an active role in the scientific debate? Should it publicly defend its turf? Should it simply do nothing and wait?

Colgate's response to date largely has been to point those who specifically ask about triclosan to the FDA's prior approval of Colgate Total. A company spokeswoman points to **a statement on the FDA website (PDF)** that says, "In 1997, FDA reviewed extensive effectiveness data on triclosan in Colgate Total toothpaste. The evidence showed that triclosan in this product was effective in preventing gingivitis." Colgate's own statement adds that since the approval, "Colgate has routinely provided FDA with updated information, consistent with the agency's guidelines, and is confident that further study will continue to add to the substantial body of research that affirms the safety of triclosan in Colgate Total."

It's a detached defense, sticking to discussion of its product and not engaging in the greater triclosan debate. What time will tell is whether Colgate is telling consumers enough to position itself best for when the FDA makes a final determination on triclosan, says **Barbara Burton** of The Burton Company in La Jolla, Calif., a corporate responsibility consultant.

"You have to determine what to disclose," she adds. "When you're not disclosing what you should, you assume risk."

Nash says the corporate social responsibility issues Colgate faces – and their impact on how the company communicates with consumers – are bound to repeat themselves in other industries and settings. He points to prominent cases from just the past year, citing **Toyota's struggle with scrutiny on accidents** involving its vehicles that were attributed by some to faulty equipment; the firestorm that **Goldman Sachs faced when securities regulators essentially accused it of cheating its customers**; and **BP's very public missteps** in the wake of its giant Gulf of Mexico oil spill. And Nash says the rules of engagement for these episodes are in constant flux. "Science changes," he adds. "Medicine changes. So does perception. So does politics. So does tolerance for risk."

Widespread Use and Unknown Impact

Triclosan is hardly just Colgate's concern, but its wide use actually makes matters trickier for the company. The chemical – first developed in the 1960s by Ciba – appears in products as varied as clothing, kitchenware, furniture, toys, and even food, says **Douglas Throckmorton**, deputy director for regulatory programs at the FDA's Center for Drug Evaluation and Research. "Every time I've asked for a list [of products using triclosan], they say, 'Beware – we're sure we're missing some,'" he says.

One of the most prominent uses, however, is in antibacterial soaps, hand sanitizers, and body washes, and that's where the current debate is centered. Throckmorton says that since 1994, the FDA has been working on its "monograph" of definitive rules governing the use of ingredients such as triclosan in these

products, and that until the work finishes, companies can use these kinds of substances. The slow progress is what inspired critics of the process to step up their arguments this year that the monograph's delay was allowing products to continue using triclosan despite new research studies indicating it is unsafe.

It's notable that Colgate isn't at the nucleus of the debate. Throckmorton says Colgate's use of triclosan doesn't fall under the proposed monograph, or even under a separate pending monograph for toothpastes, because its 1997 "new drug application" approval from the FDA was built on extensive and specific studies showing Colgate Total's "safety and efficacy" in preventing gingivitis. That means even if the agency were to ban triclosan from hand soaps, Colgate could still use it in Colgate Total.

For now, the scientific dispute has several fronts. Throckmorton says the FDA's announcement in April that it was coordinating with the EPA and other agencies to further study triclosan stems from research studies in recent years analyzing the chemical's potential impact on animal reproductive systems; its possible carcinogenic effects on skin; its widespread appearance in environmental and population samples; and its role in anti-microbial resistance. One of the biggest concerns is its potential as an "endocrine disruptor," which means that it can alter hormone behavior.

Most recent studies have traced triclosan's impact on animals, although its pervasiveness in humans is clear. The federal **Centers for Disease Control and Prevention reported** several years ago that it found triclosan in the urine of three-quarters of participants in a 2,500-person health survey.

Some public health advocacy groups say growing evidence points to triclosan's negative health effects, and have urged the FDA to act swiftly. The Natural Resources Defense Council filed a lawsuit against the FDA in July 2010 to force the agency to finish its soaps monograph. And the FDA's April announcement to step up its review appears to have been pushed by inquiries from Rep. Edward Markey of Massachusetts, who chairs a House panel on energy and the environment and has asked the agency to restrict triclosan use.

Arguing the opposite case have been triclosan's defenders, particularly chemical companies that make the substance for commercial use as well as industry groups such as the **American Cleaning Institute**, which dismisses the critics as fear-mongers and contends that products with the substance have been used safely for decades in homes, hospitals, and offices.

Colgate has been on the periphery of the debate because of its special approval status. But any negative finding against triclosan would undoubtedly impact the company. And both NRDC and Markey have called on the FDA to revisit its approval of triclosan in Colgate Total.

"We didn't have data on the endocrine disruptor effect when it was approved," says **Sarah Janssen**, senior scientist for NRDC. "We have asked the FDA to review those applications and determine whether it really does meet that bar of being safe."

Exposure and Disclosure

As the triclosan debate swirls, Colgate has planted itself behind the FDA's 1997 blessing of Colgate Total as well as similar endorsements, such as the product's clearance for use in 173 countries and seals of approval from dental associations. The spokeswoman declines to go beyond the company's basic statement, saying, "We are unavailable to further discuss." It also is not openly combating the critics raising general questions about the chemical.

McMahon DeGulis partner Nash says Colgate is "absolutely entitled" to stand on its FDA approval as a valid response to questions.

But that doesn't dismiss the question of whether Colgate ought to tell customers about the broader argument over triclosan's safety. Burton, the consultant, says the tide is turning toward greater disclosure, particularly with initiatives such as the United Nations Global Compact and the development of the **International Organization for Standardization's 26000 standard** on social responsibility, which calls for broad transparency with stakeholders on matters related to product safety.

"You don't want to take the chance of not disclosing information about potential safety concerns," she says.

She adds that while wide disclosure in a case like Colgate's could have a negative short-term impact on market share, it also could generate long-term customer good will.

However, in instances as messy as the triclosan safety debate, there is also risk of disclosing data that simply breeds confusion, says **Ken Strassner** of Strassner Consulting in Sandy Springs, Ga. "I do not believe that you have to automatically disclose everything," he adds. "There is a fair amount of consumer research that shows people don't understand the science."

There is also the concern of disclosing information that could wrongly inflame fear among customers. "We talk to our clients about being transparent, but doing it in a smart, responsible way," Nash says.

Indeed, a company faces risk management questions if inappropriate disclosure exposes "the company to frivolous legal action [or risk] to its share price or to the investing community," he adds.

In order to decide what to disclose, Strassner says a company must fully understand the "best available science."

That's also critical for risk management, because a company needs to vet the "credibility and validity of the data," as well as the scientists conducting the studies, to ensure "advocacy science" is not driving decisions, Nash says.

Strassner also says a company in Colgate's situation should stay engaged in the overall review, offering its technical expertise and input on findings. "I would participate in these processes in an open, straight-forward, technical way," he adds. "I'm not suggesting you run to the head of FDA and say 'Kill the investigation.'"

If Colgate's case underscores how balancing socially responsible conduct with company interests is more than ever a tightrope walk, it also should remind corporate leaders that such challenges are sure to multiply.

"We're in a very complex society with very complex technology," Nash says. "Frankly, this kind of stuff is going to come up again, and I think it's going to come more frequently."

Tom Stabile has worked as a reporter and editor for 19 years at magazines, newspapers, and trade publications in New York, Washington, D.C., and Santo Domingo covering business, education, government, criminal justice, and the arts.