REMAPPING DEBATE
Asking "Why" and "Why Not"

Chronic under-regulation

Original Reporting | By Abby Ferla | Health, Regulation

September 7, 2011 — Regulatory failures are often reported in isolation from one another. In one news cycle, it is the Minerals Management Service that takes "a lax attitude toward overseeing [oil drilling] operations." In another news cycle, it is the Securities and Exchange Commission that, almost without exception, refuses to prosecute those individuals and entities in the financial services industry who were apparently engaged in mortgage-securities fraud.

PUTTING REGULATORY FAILURES IN CONTEXT

Remapping Debate's specialty is original reporting. But in this case, we thought that it would be useful to build on the work of others. By compiling previous reporting that has been done on individual instances of regulatory failure, a picture quickly emerges that is very different from the bogeyman of *overregulation*: an unmistakeable, systemic pattern of *underregulation*.

Beginning with this edition's feature on the strikingly limited extent to which the Food and Drug Administration has regulated the cosmetics industry, each installment of our series will look at one regulatory agency and examine the ways in which the agency has failed to fulfill its promise of robust public protection consistently over time.

The series will conclude later this fall with original reporting that explores further the key reasons for the failures that have continued to recur, looking both at agencies that have themselves been unwilling to exercise their powers and at the external hurdles that are placed in the path of agencies that seek to regulate more aggressively.

— Editor

But when one steps back from individual stories, it is apparent that, over at least the last 30 years, a series of similar problems has undermined the ability of agencies to protect the public. These problems include a lack of statutory authority, a failure to write appropriate regulations even where necessary statutory authority exists, a lack of willingness to enforce the regulations that are on the books, and deep and chronic underfunding.

These obstacles are sometimes fueled by an administration's or a political party's hostility to an agency's mission, sometimes by Congressional indifference, and, almost always, by resistance from industries seeking to evade effective oversight. These roadblocks to effective regulation — singly and in combination — recur again and again, both across administrations and across agencies.

The Food and Drug Administration (FDA) is a good case in point, and, while there are a host of areas in which agency performance has been criticized, this article limits its scope to matters related to cosmetics safety.

The agency is authorized by the Food, Drug, and Cosmetic Act of 1938 to regulate cosmetic products — in interstate commerce — that are adulterated either through false labeling, toxic contents, or damage.

The agency, however, is still not authorized to test cosmetics before they are put on the market or to mandate recalls of dangerous products. It also still cannot require cosmetic manufacturers to register with the FDA, file information on their ingredients, or report any cosmetic-related injuries. Since the creation of the Food, Drug, and Cosmetic Act, Congress has updated laws relating to labeling regulation (1967) and given the FDA authority to regulate color additives in cosmetics (1962). Otherwise, the cosmetics-related provisions have remained largely unchanged since 1938.

For more than 30 years now, questions have been raised about the efficacy of federal efforts to assure consumers that they cosmetics they use are safe. This story recounts some of those questions, including those regarding the FDA's vigor in utilizing the statutory authority it does have in the area of cosmetics safety, those about its interest in pushing to expand that authority further, and those about Congressional receptivity to changing the status quo.

When sources are available online, we link to them. When not available online, we cite them in the endnotes.

Big industry with a history of limited oversight:

Some highlights of the research

1978: General Accounting Office study highlights limiations on FDA authority to regulate cosmetics industry and criticizes FDA for failing to use existing authority robustly.

1984: Advocacy group report finds that beauticians who use hair dyes regularly in their work have above-average cancer rates.

1988: Subcommittee of House Committee on Small Business holds hearing on safety of cosmetics. Emergency rooms said to have treated 47,000 cosmetics-related injuries in previous year. FDA and other regulatory entities called “toothless pit bulls,” with press coverage identifying major limitations in government oversight of cosmetics industry.

1990: GAO report is critical of both the existing voluntary cosmetic regulation program and of FDA enforcement.

1997: Study finds dyes for darkening gray hair may leave harmful lead residue that can be ingested, which is especially threatening to children. FDA overhaul bill that would, among other things, establish standardized labeling and warning requirements for cosmetics introduced in Congress.

2001: University of Southern California study finds above-average bladder cancer rates in beauticians that work with hair dyes. European Union conducts follow-up study, and, in response, strengthens cosmetics regulation in the EU.

2005: California requires manufacturers to report carcinogens in their products, including those in cosmetics, to the state and authorizes regulation of such products.

2007: Consumer group finds that 61 percent of tested lipstick samples contain lead above levels allowed in food.

2009: Legislation that would increase FDA authority to regulate cosmetics dies in committee.

2010: California and Oregon each find high levels of formaldehyde in hair straightening product. The proposed federal Safe Cosmetic Act of 2010 dies in committee.

2011: Revised version of 2010 proposed legislation, the Safe Cosmetic Act of 2011, is introduced.

1978

General Accounting Office (GAO, since 2004 the "Government Accountability Office") reports that cosmetic products use at least 100 chemicals listed as suspected carcinogens in the National Institute of Occupational Safety and Health's Registry of Toxic Effects of Chemical Substances. According to the Office's research, toxic chemicals could be found in at least eight hair dyes available for sale.[1]

A GAO representative tells a House subcommittee that the "FDA lacks authority to require compliance with the regulations it does set, does not have authority to require testing and has been refused access to records such as formulas used and consumer complaints because it has no authority to require such records."

The GAO is also critical of the FDA for "alleged laxity of enforcement of existing federal cosmetics law." Though the FDA is authorized to inspect plants, sample products, and require warning labels, the GAO charges that agency efforts in all of these areas have been inadequate and that the FDA has failed to "establish regulations limiting color additives that are not safe for use in cosmetics and for not establishing tests for safety evaluation of cosmetics."

FDA cites inadequate resources as a cause of lack of enforcement and asks for repeal of legislative ban on regulating hair dyes as well as authority to require testing and agency approval.

Meanwhile, the cosmetics industry asserts safety of its products and claims that self-regulation is wholly effective. The manufacturer of Grecian Formula 16, a hair dye that the GAO study alleges contains lead acetate, says that its products only have only minute amounts of the carcinogen. It tells the Washington Post that the study is "irresponsible."

1984

The National Commission on Working Women, a division of the Washington-based advocacy group Wider Opportunities for Women, releases a report entitled, "Caution: Your Work May be Hazardous to Your Health." One major finding of the report is that the chemicals in hair dyes and cosmetics impair the health of hair-dressers and cosmetologists, as evidenced by the higher rates of breast, genital, digestive, and respiratory cancers found in workers in these trades than in the overall female population. (The Commission's report is focused on Occupaational Health and Safety Administration and does not address FDA responsibility.)

A United Press International article reports that both toxic chemicals used in the workplace and rates of skin disease in employees are on the rise. Additionally, the article suggests that the FDA learns about only a small fraction of the amount of cosmetic-related consumer complaints that the manufacturers receive.

1988

In September, a subcommittee of the House Committee on Small Business holds a hearing on cosmetic safety. Newsday reports that the cosmetic industry uses over a thousand chemicals on the federal list of toxic chemicals, but that — because the FDA has no authority to test cosmetics and manufacturers are not required to report consumer complaints to the FDA — the government lacks knowledge of the health effects of these substances in cosmetics. “What the government does know is that the side effects can range from minor skin and eye irritations to tumors and nervous system damage,” Newsday writes.[2]

The subcommittee learns that emergency rooms treated 47,000 cosmetics-related injuries in the previous year and that the FDA is only using 2.5 percent of its budget to regulate cosmetics.

The United Commercial Workers International Union asks the subcommittee to implement legislation that will allow the FDA to test products before consumers suffer injuries.

Subcommittee Chairman Ron Wyden (D-Ore.) releases a statement that calls the FDA “no better than toothless pit bulls,” arguing that the FDA “regulates this business at the pleasure of the industry, with an unprecedented burden of proof placed on the agency to demonstrate harm.”

The FDA responds by saying that it uses the majority of its budget to regulate what it perceives to be more dangerous industries: food and drugs.[3]

Cosmetics industry argues that the FDA doesn’t need to have or use regulatory power over cosmetics, because the industry’s products are “extremely safe.”[4]

1990

Following the 1988 subcommittee hearing, Wyden requests that the GAO conduct a study on the safety of cosmetics. One finding of the GAO study is that the "FDA has no plans to do safety review of toxic chemicals," meaning that it has not committed personnel or funding to studying and ranking the safety of 884 chemicals used in cosmetics that are currently listed in the Registry of Toxic Effects of Chemical Substances.

The GAO also reports that, because the FDA has no authority to mandate participation in the voluntary registration program, the agency cannot accurately determine how many companies are participating. "In addition," it writes, "FDA has not assessed whether industry efforts have resulted in increased reporting of data on safety testing. Because it is a voluntary program, however, FDA will never be able to require reporting from all companies."

Newspapers across the country run stories in response to the report. One article in USA Today quotes Wyden saying, "This report very clearly contradicts the industry's claim that self-regulation works. It's another example of how the regulatory system has not kept up with the times – like riding around in a Model T in the Space Age." Wyden writes in another USA Today column that, as early as 1962, President John F. Kennedy had argued for tighter restrictions on cosmetics.

The industry responds in its own column by saying that it has an unparalleled safety record. It explains that the regulation of the cosmetic industry will divert funds away from more the dangerous industries of food and drugs. "Let's not fritter away our time and tax dollars trying to solve a non-existent problem," the column contends.

Feb. 1997

A report published in the Feb. 4 edition of the Journal of the American Pharmaceutical Association reveals that dyes for darkening gray hair contain lead that may leave a residue on the surfaces that they come into contact with. If the residue then gets on hands and is ingested – a particular risk in households with children – it can be easily absorbed into the blood stream. The report reveals that some hair dyes – particularly Grecian Formula 16 – have 10 times the lead concentration that is legally allowed in household paints. An article in Reuters says, "Studies show that lead exposure is particularly harmful to the developing brain and nervous system of fetuses and young children. The main effects of exposure include learning deficits and 'disruptive behavior.'"[5]

The FDA tells the San Francisco Chronicle that it will investigate the study's findings but that recommending recall at this stage would be "premature."

Manufacturers tell the Chronicle that "lead acetate is a safe ingredient in hair dyes."

Researchers advocate better labeling and laws that would prohibit the sale of hair dyes containing lead.

The Center for Environmental Health successfully sues to have a warning label put on Grecian Formula hair dyes. The AP writes, "FDA reports from 1978 found enough lead absorbed through the skin after use of Grecian Formula to trigger a mandatory customer warning under state law."

Combe, Inc., manufacturer of the product, calls the lawsuit "bogus."[6]

Sept. 1997

A bill to overhaul the FDA is introduced in Congress. According to the Chicago Tribune, one provision of the bill would be to "establish uniform, national labeling and warning requirements for cosmetics." Proponents of cosmetics reform, including Sen. Ted Kennedy (D-Mass.) oppose the provision, because it would prohibit states from making their own regulations regarding cosmetics. Specifically, senators from California attempt to block the provision, because it would, as the Copley news Service reports, override California's Proposition 65, which would require all companies in California to disclose information about known carcinogens and birth-defect causing chemicals in their products to the state.[7] Sen. Dianne Feinstein (D-Calif.) says in a statement, "Proposition 65 has been very effective in eliminating carcinogens and reproductive toxins in foods, drugs, and cosmetics."[8] The bill passes but without the provision dealing with national standards and preemption of state regulation.

2001

A study done at the University of Southern California gets media attention for finding that both hair colorists and women who dye their hair have higher risks of developing bladder cancer than does the general female population.

A month later, an article in the USC Wire reports that the European Union and Commission took note of the study and conducted their own research, which supported the original conclusions. In response, the EU has taken steps to regulate hair dye chemicals. However, as the Wire writes, "in the United States, the FDA does not have the authority to report cosmetic-related injuries or require manufacturers to file data on the ingredients of their products."

2005

California passes a bill that requires manufacturers to report all known carcinogens in their products to the state, which will then publicize the information and regulate these products accordingly. One California spokesperson says that the legislation is "the strongest bill in the nation to protect cosmetic consumers." According to the San Francisco Chronicle, "Manufacturers said that the law would impose California-specific rules on an international industry and that further regulation of cosmetics should be handled at the federal level."

2007

The Campaign for Safe Cosmetics releases the results of a study in which 61 percent of 33 lipsticks tested contained lead in levels six times higher than FDA standards for candy.

According to the Associated Press, an FDA spokesperson responds that periodic allegations about lead in lipstick have not been supported by FDA findings but that the agency will look into the matter.

Lipstick makers maintain that their products are safe. Cosmetic industry groups say consumers risk more lead exposure in their everyday life than they do from lipstick use.

Sens. John Kerry (D-Mass.), Barbara Boxer (D-Calif.), and Dianne Feinstein (D-Calif.) write a letter to the FDA urging it to research lipstick and issue voluntary guidelines for permissible levels. Kerry says, "There has been a continuous flow of unnerving news in recent months about the FDA's clear lack of oversight and inspection. Washington is gambling with our health, whether we are aware of it or not. It's time for the FDA to start taking this responsibility more seriously."

Jan. 2009

Former House Energy and Commerce Chairman John Dingell (D-Mich.), House Subcommittee on Health Chairman Frank Pallone (D-N.J.), and House Subcommittee on Oversight and Investigations Chairman Bart Stupak (D-Mich.) introduce a bill to reform the FDA. Called the Food and Drug Administration Globalization Act of 2009, the bill contains a provision intended "to improve the safety of cosmetic products by requiring registry of all cosmetic facilities serving the U.S. and requiring adverse event reporting," according to CongressNow.[9] The bill dies in committee.

2010

California files a lawsuit against Brazilian Blowout, a company that markets hair-straightening products. California claims that the product contains formaldehyde.

Meanwhile Oregon's Occupational Safety and Health Administration warns hairstylists that its researchers have found "significant formaldehyde levels" in Brazilian Blowout and other hair straighteners. On average, formaldehyde, a known carcinogen, constitutes 8 percent of the contents of the Brazilian Blowout samples tested. Some of the samples containing formaldehyde were taken from bottles labeled "formaldehyde-free."

As reported by the Oregonian, the company responds by criticizing the agency's research methods and maintains that its product is safe. Consumers and hairdressers, however, tell the paper that they experienced negative health effects, such as nosebleeds and chest pain, while using Brazilian Blowout.

Reps. Jan Schakowsky (D-Ill.), Ed Markey (D-Mass.), and Tammy Baldwin (D-Wisc.) introduce the Safe Cosmetics Act of 2010. If passed, the act will update the still-in-force cosmetics-related provisions of the 1938 Food and Drug Act so that the FDA will be given the authority and the funding to pre-approve cosmetic products before they are put on the shelf. The act dies in committee because of claims that it will hurt small business.

Specifically, independent and small cosmetic manufacturers, such as the Indie Beauty Network, assert that "this bill treats a company making 100 bottles of lotion each year the same way it treats a multi-billion dollar multi-national company making 100 bottles of lotion each year." They say that labeling and testing requirements will place an undue burden on small companies.

2011

The Safe Cosmetics Act of 2011, a revised version of the 2010 bill, is introduced by Schakowsky, Markey, and Baldwin. In a press release, Schakowsky says, “Currently, manufacturers are not required to disclose all their ingredients on labels and the FDA has no power to supervise the use of toxic chemicals in cosmetics. Americans are left in the dark about harmful mystery ingredients in personal care products; consumers deserve confidence that the products that they use will not hurt them.”

The Washington Times reports that business interest groups respond by saying that the bill would raise prices, hurt consumers, and hurt the industry. Industry maintains that voluntary regulation is efficient and that products are safe, saying that fears about formaldehyde are exaggerated because “the formaldehyde you get exposed to is more when you eat brussel sprouts than when you use cosmetics.” One industry member tells the Washington Times, “Unfortunately, there’s been some misinformation that’s going out there that these things are unsafe and that they aren’t tested when actually they are.”

Endnotes

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5. H. W. Mielk , M. D. Taylor, C. R. Gonzalez, M. K. Smith, P. V. Daniels, and A. V. Buckner, “Lead-Based Hair Coloring Products: Too Hazardous for Household Use,” Journal of the American Pharmaceutical Association 37.1 (1997): 85-89. Print.

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