15. Safety and Health Regulation

"The atmosphere of officialdom would kill anything that breathes the air of human endeavour, would extinguish hope and fear alike in the supremacy of paper and ink."

– Joseph Conrad, *The Shadow-Line*, 1915

"Before OSHA was created 43 years ago, an estimated 14,000 workers were killed on the job every year. … Today, workplaces are much safer and healthier. We've gone from 38 fatal injuries a day to 12. But there is still much work to be done."

– David Michaels, Assistant Secretary of Labor for Occupational Safety and Health, 2014

Introduction

Tort law generally works in an *ex post* manner. The phrase *ex post* is short for *ex post facto,* which is Latin for "after the fact." For the most part, when tort law comes in, the damage has already been done. Thus, tort law is largely about shifting the burden of loss from one party to the other, thus making the best of a bad situation. Nevertheless, because tort law provides a way of shifting the burden of loss after the fact, it undoubtedly has a strong – albeit indirect – effect of preventing harm: The anticipation of being forced to pay after-the-fact damages will incentivize persons to be more careful on the front end.

The courts do have a more direct role to play in the prevention of accidents and injuries. Although rarely invoked, basic principles of equity can be used to get a court to order an injunction prohibiting conduct that is deemed unreasonably risky. In *Harris Stanley Coal & Land Co. v. Chesapeake & Ohio Railway Co.,* 154 F.2d. 450 (6th Cir. 1946), a railroad running on tracks above an underground coal mine

won an injunction to prohibit the mine from conducting an operation called "pulling the pillars," in which columns of coal originally left intact to support the mine's ceiling would be demolished so that the coal could be recovered. The railroad argued that pillar-pulling operations could cause the ground underneath the train to subside, leading to a derailment. The court agreed with the railroad, deciding that when lives were at stake, an *ex post* award of damages would not be adequate to set things right again.

Court orders to halt risky activities are, however, infrequent. By far, the most common way for the law to try to directly prevent accidents and injuries is through ***administrative regulation***. Unlike the relatively few general principles of tort law, government regulations are legion, and their provisions can be extraordinarily specific.

The Code of Federal Regulations, which contains the federal body of regulatory law, fills about 200 volumes when printed in book form. Not all of that concerns safety. Many regulations govern the distribution of various government-granted entitlements – everything from patents to Social Security payments. Another large fraction concerns taxes and tariffs. But notwithstanding these varied subjects, it is fair to say that preventing injuries, accidents, health problems, and other tort-type harms is a major preoccupation of federal regulation. Safety regulations run the gamut from 49 C.F.R. §382.207, which prohibits commercial-vehicle drivers from performing "safety-sensitive functions" within four hours of drinking alcohol, to 21 C.F.R. §556.200, which limits concentrations of the antibiotic dihydrostreptomycin in swine kidney meat to 2.0 parts per million.

Specific regulations of this sort are subordinate to a layer of law that governs the authority of agencies to make and enforce regulations, as well as the ability of citizens to challenge agency actions. This body of law is known as ***administrative law***, and it is the focus of an upper-division elective course at most law schools.

The object of this chapter is not to comprehensively teach you administrative law, nor to teach you the substance of the huge body of regulatory law of the United States. Rather, the aim is to give you a feel for how agencies use regulation to prevent injury and to allow

you to see the regulatory system as counterpoint to the common-law scheme of torts.

History of Administrative Regulation

Through most of the 1800s, there were fewer than a dozen federal agencies. With industrialization, federal agencies began to multiply and take on a greater role in governance and the economy. In this earlier stage of the administrative state, much of the function of agencies was rate regulation. The Interstate Commerce Commission, for instance, established by the Interstate Commerce Act of 1887, regulated the rates charged by common carriers such as railroads and telegraph companies. The aim was to prevent such companies from using their natural monopoly power to engage in rate discrimination that would be unfair to consumers and that could stifle the economic growth.

The blossoming of administrative agencies as a means of *ex ante* prevention of personal harm occurred in the 20th Century. A turning point occurred in 1906, when public disgust with the meat-packing industry was brought on by Upton Sinclair's novel, *The Jungle.* Congress responded with a wave of regulation.

The true boom years of administrative agency creation occurred from the 1930s through the 1970s. In response to the Great Depression, Franklin D. Roosevelt's New Deal programs massively increased the size and scope of the federal administrative state. Then, after World War II, Congress brought organization to the administrative system with the Administrative Procedure Act of 1946. The project of building the government bureaucracy continued through the increasing economic sophistication of industry in the 1950s and 60s, and the environmental movement of the 1970s.

The 1980s saw a growing skepticism of regulation, part of larger movement against "big government." A widely held sentiment of the era is typified by President Ronald Reagan's cynical quip about the role of government: "If it moves, tax it. If it keeps moving, regulate it. And if it stops moving, subsidize it."

If Reagan's presidency marked a new era of distrust of administrative regulation, it did not by any means mark the end of the administrative power. Today the number of federal agencies is probably in the thousands, although, in a boon to critics, the government itself has been unable to pin down an exact figure.

Reading: *The Jungle*

At the dawn of the 20th Century the work of butchering animals for meat, which had previously been done on a local basis, became centralized in huge meat-packing operations. The biggest concentration of slaughtering and butchering activity was in Chicago's "Packingtown."

With market power concentrated in just four companies, and given a stream of willing immigrant laborers arriving from overseas, the packing industry was able to impose extremely harsh working conditions. When the packing companies broke a meat-worker's strike in 1904, a socialist magazine, *Appeal to Reason*, prodded 26-year-old New York City writer Upton Sinclair to go to Chicago to investigate. Over two months, he conducted interviews and witnessed factory operations firsthand. His product was a serialized novel published in the magazine. Sinclair's subsequent attempts to publish the manuscript as a book met with failure until he paid for the first printing himself in February 1906. The book then caused a sensation, and the political forces it helped unleash changed the face of American law.

The Jungle

a novel by
Upton Sinclair

February 1906

> Jurgis was confident of his ability to get work for himself, unassisted by any one. As we have said before, he was not mistaken in this. He had gone to Brown's and stood there not more than half an hour before one of the bosses noticed his form towering above the rest, and signaled to him. The colloquy which followed was brief and to the point:

"Speak English?"

"No; Lit-uanian." (Jurgis had studied this word carefully.)

"Job?"

"Je." (A nod.)

"Worked here before?"

"No 'stand."

(Signals and gesticulations on the part of the boss. Vigorous shakes of the head by Jurgis.)

"Shovel guts?"

"No 'stand." (More shakes of the head.)

"Zarnos. Pagaiksztis. Szluofa!" (Imitative motions.)

"Je."

"See door. Durys?" (Pointing.)

"Je."

"To-morrow, seven o'clock. Understand? Rytoj! Prieszpietys! Septyni!"

"Dekui, tamistai!" (Thank you, sir.) And that was all. Jurgis turned away, and then in a sudden rush the full realization of his triumph swept over him, and he gave a yell and a jump, and started off on a run. He had a job! He had a job! And he went all the way home as if upon wings, and burst into the house like a cyclone, to the rage of the numerous lodgers who had just turned in for their daily sleep.

For one evening the old man came home in a great state of excitement, with the tale that he had been approached by a man in one of the corridors of the pickle rooms of Durham's, and asked what he would pay to get a job. He had not known what to make of this at first; but the man had gone on with matter-of-fact frankness to say that he could get him a job, provided that he were willing to pay one-third of his wages for it. Was he a

boss? Antanas had asked; to which the man had replied that that was nobody's business, but that he could do what he said.

Jurgis had made some friends by this time, and he sought one of them and asked what this meant. The friend, who was named Tamoszius Kuszleika, was a sharp little man who folded hides on the killing beds, and he listened to what Jurgis had to say without seeming at all surprised. They were common enough, he said, such cases of petty graft. It was simply some boss who proposed to add a little to his income. After Jurgis had been there awhile he would know that the plants were simply honeycombed with rottenness of that sort – the bosses grafted off the men, and they grafted off each other; and some day the superintendent would find out about the boss, and then he would graft off the boss. Warming to the subject, Tamoszius went on to explain the situation. Here was Durham's, for instance, owned by a man who was trying to make as much money out of it as he could, and did not care in the least how he did it; and underneath him, ranged in ranks and grades like an army, were managers and superintendents and foremen, each one driving the man next below him and trying to squeeze out of him as much work as possible. And all the men of the same rank were pitted against each other; the accounts of each were kept separately, and every man lived in terror of losing his job, if another made a better record than he. So from top to bottom the place was simply a seething caldron of jealousies and hatreds; there was no loyalty or decency anywhere about it, there was no place in it where a man counted for anything against a dollar. And worse than there being no decency, there was not even any honesty. The reason for that? Who could say? It must have been old Durham in the beginning; it was a heritage which the self-made merchant had left to his son, along with his millions.

Jurgis would find out these things for himself, if he stayed there long enough; it was the men who had to do all the dirty jobs, and so there was no deceiving them; and they caught the spirit of the place, and did like all the rest. Jurgis had come there, and thought he was going to make himself useful, and rise and become a skilled man; but he would soon find out his error –

for nobody rose in Packingtown by doing good work. You could lay that down for a rule – if you met a man who was rising in Packingtown, you met a knave. That man who had been sent to Jurgis' father by the boss, he would rise; the man who told tales and spied upon his fellows would rise; but the man who minded his own business and did his work – why, they would "speed him up" till they had worn him out, and then they would throw him into the gutter.

Jurgis went home with his head buzzing. Yet he could not bring himself to believe such things – no, it could not be so. Tamoszius was simply another of the grumblers. He was a man who spent all his time fiddling; and he would go to parties at night and not get home till sunrise, and so of course he did not feel like work. Then, too, he was a puny little chap; and so he had been left behind in the race, and that was why he was sore. And yet so many strange things kept coming to Jurgis' notice every day!

He tried to persuade his father to have nothing to do with the offer. But old Antanas had begged until he was worn out, and all his courage was gone; he wanted a job, any sort of a job. So the next day he went and found the man who had spoken to him, and promised to bring him a third of all he earned; and that same day he was put to work in Durham's cellars. It was a "pickle room," where there was never a dry spot to stand upon, and so he had to take nearly the whole of his first week's earnings to buy him a pair of heavy-soled boots. He was a "squeedgie" man; his job was to go about all day with a long-handled mop, swabbing up the floor. Except that it was damp and dark, it was not an unpleasant job, in summer.

Now Antanas Rudkus was the meekest man that God ever put on earth; and so Jurgis found it a striking confirmation of what the men all said, that his father had been at work only two days before he came home as bitter as any of them, and cursing Durham's with all the power of his soul. For they had set him to cleaning out the traps; and the family sat round and listened in wonder while he told them what that meant. It seemed that he was working in the room where the men prepared the beef for

canning, and the beef had lain in vats full of chemicals, and men with great forks speared it out and dumped it into trucks, to be taken to the cooking room. When they had speared out all they could reach, they emptied the vat on the floor, and then with shovels scraped up the balance and dumped it into the truck. This floor was filthy, yet they set Antanas with his mop slopping the "pickle" into a hole that connected with a sink, where it was caught and used over again forever; and if that were not enough, there was a trap in the pipe, where all the scraps of meat and odds and ends of refuse were caught, and every few days it was the old man's task to clean these out, and shovel their contents into one of the trucks with the rest of the meat!

This was the experience of Antanas; and then there came also Jonas and Marija with tales to tell. Marija was working for one of the independent packers, and was quite beside herself and outrageous with triumph over the sums of money she was making as a painter of cans. But one day she walked home with a pale-faced little woman who worked opposite to her, Jadvyga Marcinkus by name, and Jadvyga told her how she, Marija, had chanced to get her job. She had taken the place of an Irishwoman who had been working in that factory ever since any one could remember. For over fifteen years, so she declared. Mary Dennis was her name, and a long time ago she had been seduced, and had a little boy; he was a cripple, and an epileptic, but still he was all that she had in the world to love, and they had lived in a little room alone somewhere back of Halsted Street, where the Irish were. Mary had had consumption, and all day long you might hear her coughing as she worked; of late she had been going all to pieces, and when Marija came, the "forelady" had suddenly decided to turn her off. The forelady had to come up to a certain standard herself, and could not stop for sick people, Jadvyga explained. The fact that Mary had been there so long had not made any difference to her – it was doubtful if she even knew that, for both the forelady and the superintendent were new people, having only been there two or three years themselves. Jadvyga did not know what had become of the poor creature; she would have gone to see her, but had been sick herself. She had pains in her back all the time, Jadvyga

explained, and feared that she had womb trouble. It was not fit work for a woman, handling fourteen-pound cans all day.

It was a striking circumstance that Jonas, too, had gotten his job by the misfortune of some other person. Jonas pushed a truck loaded with hams from the smoke rooms on to an elevator, and thence to the packing rooms. The trucks were all of iron, and heavy, and they put about threescore hams on each of them, a load of more than a quarter of a ton. On the uneven floor it was a task for a man to start one of these trucks, unless he was a giant; and when it was once started he naturally tried his best to keep it going. There was always the boss prowling about, and if there was a second's delay he would fall to cursing; Lithuanians and Slovaks and such, who could not understand what was said to them, the bosses were wont to kick about the place like so many dogs. Therefore these trucks went for the most part on the run; and the predecessor of Jonas had been jammed against the wall by one and crushed in a horrible and nameless manner.

All of these were sinister incidents; but they were trifles compared to what Jurgis saw with his own eyes before long. One curious thing he had noticed, the very first day, in his profession of shoveler of guts; which was the sharp trick of the floor bosses whenever there chanced to come a "slunk" calf. Any man who knows anything about butchering knows that the flesh of a cow that is about to calve, or has just calved, is not fit for food. A good many of these came every day to the packing houses – and, of course, if they had chosen, it would have been an easy matter for the packers to keep them till they were fit for food. But for the saving of time and fodder, it was the law that cows of that sort came along with the others, and whoever noticed it would tell the boss, and the boss would start up a conversation with the government inspector, and the two would stroll away. So in a trice the carcass of the cow would be cleaned out, and entrails would have vanished; it was Jurgis' task to slide them into the trap, calves and all, and on the floor below they took out these "slunk" calves, and butchered them for meat, and used even the skins of them.

One day a man slipped and hurt his leg; and that afternoon, when the last of the cattle had been disposed of, and the men were leaving, Jurgis was ordered to remain and do some special work which this injured man had usually done. It was late, almost dark, and the government inspectors had all gone, and there were only a dozen or two of men on the floor. That day they had killed about four thousand cattle, and these cattle had come in freight trains from far states, and some of them had got hurt. There were some with broken legs, and some with gored sides; there were some that had died, from what cause no one could say; and they were all to be disposed of, here in darkness and silence. "Downers," the men called them; and the packing house had a special elevator upon which they were raised to the killing beds, where the gang proceeded to handle them, with an air of businesslike nonchalance which said plainer than any words that it was a matter of everyday routine. It took a couple of hours to get them out of the way, and in the end Jurgis saw them go into the chilling rooms with the rest of the meat, being carefully scattered here and there so that they could not be identified. When he came home that night he was in a very somber mood, having begun to see at last how those might be right who had laughed at him for his faith in America.

Jurgis heard of these things little by little, in the gossip of those who were obliged to perpetrate them. It seemed as if every time you met a person from a new department, you heard of new swindles and new crimes. There was, for instance, a Lithuanian who was a cattle butcher for the plant where Marija had worked, which killed meat for canning only; and to hear this man describe the animals which came to his place would have been worthwhile for a Dante or a Zola. It seemed that they must have agencies all over the country, to hunt out old and crippled and diseased cattle to be canned. There were cattle which had been fed on "whisky-malt," the refuse of the breweries, and had become what the men called "steerly" – which means covered with boils. It was a nasty job killing these, for when you plunged your knife into them they would burst and splash foul-smelling stuff into your face; and when a man's sleeves were smeared

with blood, and his hands steeped in it, how was he ever to wipe his face, or to clear his eyes so that he could see? It was stuff such as this that made the "embalmed beef" that had killed several times as many United States soldiers as all the bullets of the Spaniards; only the army beef, besides, was not fresh canned, it was old stuff that had been lying for years in the cellars.

Then one Sunday evening, Jurgis sat puffing his pipe by the kitchen stove, and talking with an old fellow whom Jonas had introduced, and who worked in the canning rooms at Durham's; and so Jurgis learned a few things about the great and only Durham canned goods, which had become a national institution. They were regular alchemists at Durham's; they advertised a mushroom-catsup, and the men who made it did not know what a mushroom looked like. They advertised "potted chicken," – and it was like the boardinghouse soup of the comic papers, through which a chicken had walked with rubbers on. Perhaps they had a secret process for making chickens chemically – who knows? said Jurgis' friend; the things that went into the mixture were tripe, and the fat of pork, and beef suet, and hearts of beef, and finally the waste ends of veal, when they had any. They put these up in several grades, and sold them at several prices; but the contents of the cans all came out of the same hopper. And then there was "potted game" and "potted grouse," "potted ham," and "deviled ham" – de-vyled, as the men called it. "De-vyled" ham was made out of the waste ends of smoked beef that were too small to be sliced by the machines; and also tripe, dyed with chemicals so that it would not show white; and trimmings of hams and corned beef; and potatoes, skins and all; and finally the hard cartilaginous gullets of beef, after the tongues had been cut out. All this ingenious mixture was ground up and flavored with spices to make it taste like something. Anybody who could invent a new imitation had been sure of a fortune from old Durham, said Jurgis' informant; but it was hard to think of anything new in a place where so many sharp wits had been at work for so long; where men welcomed tuberculosis in the cattle they were feeding, because it made them fatten more quickly; and where they bought up all

the old rancid butter left over in the grocery stores of a continent, and "oxidized" it by a forced-air process, to take away the odor, rechurned it with skim milk, and sold it in bricks in the cities! Up to a year or two ago it had been the custom to kill horses in the yards – ostensibly for fertilizer; but after long agitation the newspapers had been able to make the public realize that the horses were being canned. Now it was against the law to kill horses in Packingtown, and the law was really complied with – for the present, at any rate. Any day, however, one might see sharp-horned and shaggy-haired creatures running with the sheep and yet what a job you would have to get the public to believe that a good part of what it buys for lamb and mutton is really goat's flesh!

There was another interesting set of statistics that a person might have gathered in Packingtown – those of the various afflictions of the workers. When Jurgis had first inspected the packing plants with Szedvilas, he had marveled while he listened to the tale of all the things that were made out of the carcasses of animals, and of all the lesser industries that were maintained there; now he found that each one of these lesser industries was a separate little inferno, in its way as horrible as the killing beds, the source and fountain of them all. The workers in each of them had their own peculiar diseases. And the wandering visitor might be skeptical about all the swindles, but he could not be skeptical about these, for the worker bore the evidence of them about on his own person – generally he had only to hold out his hand.

There were the men in the pickle rooms, for instance, where old Antanas had gotten his death; scarce a one of these that had not some spot of horror on his person. Let a man so much as scrape his finger pushing a truck in the pickle rooms, and he might have a sore that would put him out of the world; all the joints in his fingers might be eaten by the acid, one by one. Of the butchers and floorsmen, the beef-boners and trimmers, and all those who used knives, you could scarcely find a person who had the use of his thumb; time and time again the base of it had been slashed, till it was a mere lump of flesh against which the man pressed the knife to hold it. The hands of these men would

be criss-crossed with cuts, until you could no longer pretend to count them or to trace them. They would have no nails, – they had worn them off pulling hides; their knuckles were swollen so that their fingers spread out like a fan. There were men who worked in the cooking rooms, in the midst of steam and sickening odors, by artificial light; in these rooms the germs of tuberculosis might live for two years, but the supply was renewed every hour. There were the beef-luggers, who carried two-hundred-pound quarters into the refrigerator-cars; a fearful kind of work, that began at four o'clock in the morning, and that wore out the most powerful men in a few years. There were those who worked in the chilling rooms, and whose special disease was rheumatism; the time limit that a man could work in the chilling rooms was said to be five years. There were the wool-pluckers, whose hands went to pieces even sooner than the hands of the pickle men; for the pelts of the sheep had to be painted with acid to loosen the wool, and then the pluckers had to pull out this wool with their bare hands, till the acid had eaten their fingers off. There were those who made the tins for the canned meat; and their hands, too, were a maze of cuts, and each cut represented a chance for blood poisoning. Some worked at the stamping machines, and it was very seldom that one could work long there at the pace that was set, and not give out and forget himself and have a part of his hand chopped off. There were the "hoisters," as they were called, whose task it was to press the lever which lifted the dead cattle off the floor. They ran along upon a rafter, peering down through the damp and the steam; and as old Durham's architects had not built the killing room for the convenience of the hoisters, at every few feet they would have to stoop under a beam, say four feet above the one they ran on; which got them into the habit of stooping, so that in a few years they would be walking like chimpanzees. Worst of any, however, were the fertilizer men, and those who served in the cooking rooms. These people could not be shown to the visitor, – for the odor of a fertilizer man would scare any ordinary visitor at a hundred yards, and as for the other men, who worked in tank rooms full of steam, and in some of which there were open vats near the level of the floor, their peculiar

> trouble was that they fell into the vats; and when they were fished out, there was never enough of them left to be worth exhibiting, – sometimes they would be overlooked for days, till all but the bones of them had gone out to the world as Durham's Pure Leaf Lard!

Historical Note on *The Jungle*

Sinclair hoped his novel would inspire the public to support the socialist struggle for workers' welfare. The most pronounced effect, however, was to focus the public on questions of food safety. President Theodore Roosevelt conducted his own follow-up factfinding and found conditions even worse than those described in the book. Roosevelt eventually invited Sinclair to the White House to consult on how to improve inspections. Congress was spurred to pass two landmark statutes on June 30, 1906 – the Federal Meat Inspection Act and the Pure Food and Drug Act, the later of which established the modern Food and Drug Administration.

Questions to Ponder About *The Jungle*

A. What does this reading suggest about the relative value of tort law and administrative law in preventing injuries to workers?

B. Would the injured workers have been likely to sue Durham's? Why or why not? To what extent might the relative scarcity of jobs and abundance of applicants play a role in plaintiffs' decisions to sue? What about the power dynamics within the managerial hierarchy? If they sued in tort, what would be their chances of obtaining a recovery? Considering your answers to the foregoing, to what extent do you think Durham's would adjust the working environment and operational practices as a response to prospective tort liability?

C. What does this reading suggest about the relative value of tort law and administrative law in preventing consumers from receiving adulterated foods?

D. Would the consumers who ended up eating human remains have been likely to sue Durham's? Why or why not? To what extent does the economic power of Durham's play a role in the likelihood of consumers suing? Assuming unwitting consumers of human remains

sued Durham's in tort, what causes of action could they use? And what would be the likely outcome?

Administrative Agencies and the Law Governing Them

A myriad of federal agencies produce, enforce, and interpret health and safety regulations. Some of these agencies are devoted primarily to the prevention of injury. Standout examples include the National Highway Traffic Safety Administration ("NHTSA," regulating automobile manufacture), the Occupational Safety & Health Administration ("OSHA," regulating workplace safety), and the U.S. Consumer Product Safety Commission ("the CPSC," regulating toys, tools, and other products that do not come under an agency with more specific jurisdiction). Other agencies have broader regulatory mandates, but safety is a large part of what they do – a good example being the Federal Aviation Administration ("FAA," regulating airlines and airplanes, and providing air traffic control).

Within their spheres of expertise, agencies exercise elements of legislative, judicial, and executive power. Agencies make law by promulgating regulations. They act as units of executive power by conducting investigations and bringing enforcement actions against private parties. And agencies exercise a judicial function through administrative tribunals that are presided over by administrative law judges.

Agencies are one of the most salient aspects of the anatomy of today's federal government. Yet they are not mentioned in the Constitution. Instead, agencies are created by statute, and their authority to act derives from statute. For instance, the Consumer Product Safety Act (15 U.S.C. §§ 2051-2089) established the CPSC. That same act provided the CPSC with the authority it used to ban lawn darts. (Lawn darts are huge, oversized darts that can be sued to play an outdoor game similar to horseshoes. They caused numerous deaths and brain injuries through skull punctures, many of the victims being children.) A different statute, the Federal Hazardous Substances Act of 1960 (15 U.S.C. §§ 1261-1278) gave the CPSC the authority it used to ban lead paint. (Lead is poisonous, and bits of

lead paint, when ingested or inhaled by children, can affect brain development.)

The process that an agency must follow in rulemaking or adjudication comes from statute as well. For many agencies, certain processes are dictated by the statute that first brought the agency into existence – variously called the "enabling act," "enabling legislation," or "organic act." This is the statutory law that established the agency and that, going forward, governs its essential operation. To the extent its enabling act does not specify otherwise, an agency's procedure is governed by the overarching "APA" – the Administrative Procedure Act of 1946 (5 U.S.C. §§ 500, et seq.). Amended several times since its original passage, the APA is the generic default law that applies to administrative agencies across the board.

How Regulations are Made

The APA sets out two possible methods of rulemaking.

The first, **formal rulemaking**, requires the agency to hold a proceeding similar to a courtroom trial, in which evidence is introduced on the record and a decision to promulgate a rule is based on that record. The APA, by itself, does not require this procedure. It is only required if the relevant enabling statute requires it. And few enabling statutes do. Some new regulations of the Food and Drug Administration are required to follow the formal rulemaking procedure, but for the most part, formal rulemaking is a relic of a past era when a primary concern of administrative regulation was rate-setting for railroads and the like.

The second method – and the procedure by which nearly all new regulation is promulgated – is known as **notice-and-comment rulemaking**. This method is the default procedure for rulemaking under the APA, and it applies to all regulation-creation unless a specific provision of enabling statutory law provides otherwise. Today, nearly all regulations are promulgated this way.

An alternative name for notice-and-comment rulemaking is *informal rulemaking* – but it's only "informal" in comparison to old-school formal rulemaking. First, an agency must issue an official notice of

proposed rulemaking in the Federal Register, which is a daily publication of the U.S. government. At the same time as it gives notice, the agency invites comment from interested groups and members of the public.

The comment period usually must be at least 30 days, but agencies frequently allow a longer comment period than the minimum because of a sincere interest in getting informed opinions from people who have a strong interest in the matter – "stakeholders" in agency jargon.

After receiving comments, the agency deliberates. Then, unless it has been persuaded to abandon its efforts, the agency will decide on a final rule. The final rule might be quite different than the proposed rule. In some cases, comments persuade the agency that it needs to go in a different direction than it had been contemplating with its proposed rule. If the newly contemplated rule is different enough from the original proposal, the agency must re-propose the rule in its new incarnation and solicit a new round of comments. For instance, if a proposed rule would have banned the use of a certain chemical in toys, and the new rule would ban it in all industrial and consumer settings, then the notice-and-comment process would need to be started anew to give newly implicated stakeholders a chance to weigh in.

After deciding on a final rule, most agencies in the federal government then face an additional step before officially promulgating the regulation: They must send the rule to the White House's Office of Information and Regulatory Affairs, where the president's staff can squelch the regulation or send it back to the agency with instructions to do revisions or additional research. When a rule is finally adopted, it is codified in the Code of Federal Regulations, where it has the force of law.

Depending on the relevant enabling statute, agencies can sometimes adopt an emergency regulation without providing for notice and comment ahead of time. But ordinarily such a regulation is only valid on a temporary basis. In the meantime, the agency can use the regular means of rulemaking to promulgate a permanent regulation that will be effective after the emergency regulation expires. For example,

OSHA is authorized by § 6(c) of the Occupational Safety and Health Act of 1970 to adopt "emergency temporary standards" in cases where the Secretary of Labor determines that the rule is necessary to protect workers from a "grave danger." The rule is effective as soon as it is published in the Federal Register, and it can last a maximum of six months. During that time, OSHA must use an elaborate procedure under § 6(b) of the OSHA Act involving public review and public hearings if it wants a permanent rule.

Judicial Review of Regulations

Persons opposing regulations can seek to have them overturned by judicial review. But doing so requires finding a legal basis upon which to mount a challenge.

The most powerful source for challenging a regulation may be the agency's enabling act. Agency-specific statutes sometimes provide a way to challenge rules on the merits – such as by arguing that the "problem" addressed by the rule lacks significance. On the other hand, a given enabling act may provide an agency with extra-wide discretion, in which case there may be little foothold for challengers.

As an across-the-board matter, the APA provides generic grounds for courts to set aside regulations. The first ground for overturning a regulation is finding it to be **arbitrary or capricious**. 5 U.S.C. § 706(2)(A). This is a high burden for the challenger to meet. It means that a court cannot set aside a regulation simply because the court disagrees with the agency, or even because the court is convinced the regulation is a ruinously bad idea. Arbitrary-or-capricious review means, in some sense, that the court must find that the agency has lain down on the job. Thus, arbitrary-or-capricious review is quite limited. But it does provide a way for courts to keep agency rulemaking in check at the outer boundaries.

Another key basis upon which to set aside a regulation is **failure to observe required procedure**. 5 U.S.C. § 706(2)(D). Proper procedure is very important under the APA. "Procedure" is, after all, the APA's middle name. But so long as agencies are good at following procedure – and they usually are – they can keep their regulations safe from this sort of challenge.

One sure-fire way of getting a court to overturn a regulation is convincing the court that the agency promulgating the regulation has **exceeded its statutory grant of authority** in doing so. The only thing that allows an agency to issue a regulation with the force of law is that Congress has, by law, provided the agency with the authority to do so. So if an agency exceeds it's authority, the regulation is dead in the water. Yet it is an uphill battle to persuade a court that an agency has exceeded its statutory power because of a doctrine called ***Chevron*** **deference**. Under this doctrine, named for the Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), agencies have a great deal of power to interpret their own governing statutes. This is important, because it means agencies are allowed to interpret their enabling legislation broadly, giving themselves the broadest possible regulatory power. Under *Chevron*, if Congressional intent is unclear as to the scope of agency power, then the agency can choose any permissible interpretation, and that interpretation will be deemed the correct one. From *Chevron*:

> The power of an administrative agency to administer a congressionally created program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress. If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.

Chevron, 467 U.S. at 834-44 (internal quotes, footnotes, and ellipses omitted).

The bottom line is that agencies wield tremendous quasi-legislative power, and the ability of others to challenge disliked regulations can be quite limited.

Agency Enforcement of Regulations

Administrative agencies are not only given the power to make regulations, but also to enforce them and, through administrative tribunals, to adjudicate those enforcement efforts. By putting rulemaking, enforcement, and adjudication all together in one agency with a large pool of technical expertise, agencies are able to move much faster than legislatures and courts in responding to fast-emerging questions about product safety and other health concerns. Of course, depending on whether you are a safety advocate or a business investor, that may or may not be a good thing.

Case: *FDA v. Phusion Products LLC*

In 2005, a start-up company in Ohio named Phusion began selling an alcoholic energy beverage called Four Loko. The product was a sugar-sweetened concoction of alcohol, caffeine, and additional "energy" ingredients of taurine and guarana. The idea of a drink that simultaneously relaxes and stimulates the imbiber found broad appeal. Phusion enjoyed strong sales growth. Hip-hop songs sang the drink's praises. Then, in 2010, reports surfaced connecting Four Loko to hospitalizations. Soon, multiple deaths were blamed on the beverage. A media firestorm ensued.

The safety questions caught the attention of federal regulators. In the following letter, the FDA took the position that Four Loko was unlawful because it violated federal statutory law on food safety and its accompanying regulations. The key statute, 21 U.S.C. § 342(a)(2)(C), provides: "A food shall be deemed to be adulterated ... if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title ... "

FDA v. Phusion Products LLC

Department of Health and Human Services
Public Health Service

Food and Drug Administration
College Park, MD 20740

NOV 17, 2010

WARNING LETTER

OVERNIGHT MAIL via UPS

Mr. Jaisen Freeman
Mr. Chris Hunter
Mr. Jeff Wright
Phusion Projects, LLC (dba Drink Four Brewing Company)
1658 N. Milwaukee Avenue, Suite 424
Chicago, IL 60647

Re: 134051

Dear Messrs. Freeman, Hunter, and Wright

The Food and Drug Administration (FDA) has reviewed the regulatory status of the ingredients declared on the label of your product, "Four Loko" which contains caffeine that has been directly added to an alcoholic beverage and packaged in combined caffeine and alcohol form. As it is used in your product, caffeine is an unsafe food additive, and therefore your product is adulterated under section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(2)(C)]. Regulations on the general provisions for food additives are located in Title 21, Code of Federal Regulations, Part 170 (21 CFR 170). You may find copies of the Act and these regulations through links in FDA's Internet home page at http://www.fda.gov.

As defined in section 201(s) of the Act [21 U.S.C. § 321(s)], the term "food additive" refers to any substance the intended use of which results in its becoming a component of any food, unless the substance is the subject of a prior sanction or is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use. Under section 409 of the Act [21 U.S.C. § 348], a food additive is unsafe unless a regulation is in effect that prescribes the conditions under which the additive may be safely used, and the additive and its use or intended use are in conformity with that regulation. There is no food additive regulation authorizing the use of caffeine as a direct addition to alcoholic beverages, and we are not aware of any information to establish that caffeine added directly to alcoholic beverages is the subject of a prior sanction. Likewise, we are not aware of any basis to conclude that caffeine is GRAS under these conditions of use.

FDA's regulations in 21 CFR Part 170 describe the eligibility criteria for classification of a substance added to food as GRAS. Under 21 CFR 170.30(a)-(c), general recognition of safety must be based on the views of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. Further, general recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly added to food.

FDA's regulations in 21 CFR Part 170 define "common use in food" and establish eligibility criteria for classification as GRAS through experience based on common use in food. Under 21 CFR 170.30, common use in food means "a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate

that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food. See section 201(s) of the Act [21 U.S.C. § 321(s)]; see also *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1389-90 (9th Cir. 1983) ("Under the statute, 'common use in food' of an ingredient does not automatically exempt the substance from pretesting requirements. Instead, 'common use in food' merely describes one form of evidence that may be introduced by a proponent for the purpose of meeting the ultimate standard ... ").

Similarly, FDA's regulations in 21 CFR Part 170 define "scientific procedures" and establish eligibility criteria for classification as GRAS through scientific procedures. Under 21 CFR 170.3(h), scientific procedures "include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), general recognition of safety based upon scientific procedures "shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.

FDA's regulations in 21 CFR Part 170 also define "safe" and "safety." Under 21 CFR 170.3(i), "[s]afe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulations identify factors to be considered in determining the safety of a substance added to food. 21 CFR 170.3(i).

By letter dated November 12, 2009, FDA requested that, within 30 days, your company provide evidence of the rationale, along with supporting data and information, for concluding that the use of caffeine in your product is GRAS or prior sanctioned. The letter informed your company that if FDA determined that the use of caffeine in your alcoholic beverage is neither GRAS

nor the subject of a prior sanction, the agency would take appropriate action to ensure that the product is removed from the marketplace. FDA's letter also reiterated that it is the continuing responsibility of your company to ensure that the foods it markets are safe and in compliance with all applicable legal and regulatory requirements.

FDA acknowledges that, in response to the agency's November 12 letter, your firm submitted a letter within the 30 day timeframe requested, indicating that you would submit a GRAS Notice pursuant to proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997) at a later date. The agency received your GRAS Notice (GRN No. 000347) ("GRAS Notice"), dated June 25, 2010, and filed it on June 30, 2010. But, as discussed in more detail below, FDA has reviewed that notice and continues to have safety concerns about your caffeinated alcoholic beverage product. Accordingly, the agency is issuing this warning letter.

To establish that the use of a substance in food is GRAS under its specific conditions of use (for example, the GRAS status of caffeine when directly added to an alcoholic beverage), there must be consensus among qualified experts that the substance is safe under its conditions of use, based on publicly available data and information. FDA is aware that, based on the publicly available literature, a number of qualified experts have concerns about the safety of caffeinated alcoholic beverages. Moreover, the agency is not aware of data or other information to establish the safety of the relevant conditions of use for your product. Therefore, the criteria for GRAS status have not been met for the caffeine in your beverage.

Based upon the publicly available literature, FDA has the following specific concerns about the safety of caffeine when used in the presence of alcohol.[5] As used in the discussion below, the term "energy drink" identifies beverages that contain a significant amount of calories and caffeine as well as other ingredients, such as taurine, herbal extracts, or vitamins (Heckman et al., 2010).[6]

- Reports in the scientific literature have described behavioral effects that may occur in young adults when

energy drinks are consumed along with alcoholic beverages (O'Brien et al., 2008; Thombs et al., 2010; Miller, 2008).

- Studies suggest that the combined ingestion of caffeine and alcohol may lead to hazardous and life-threatening situations because caffeine counteracts some, but not all, of alcohol's adverse effects. In one study, a mixture of an energy drink and alcohol reduced subjects' subjective perception of intoxication but did not improve diminished motor coordination or slower visual reaction times using objective measures (Ferreira et al., 2006). In a dual-task model, subjects co-administered caffeine and alcohol reported reduced perception of intoxication but no reduction of alcohol-induced impairment of task accuracy (Marczinski and Fillmore, 2006).

- Because caffeine alters the perception of alcohol intoxication, the consumption of pre-mixed products containing added caffeine and alcohol may result in higher amounts of alcohol consumed per drinking occasion, a situation that is particularly dangerous for naïve drinkers (Oteri et al., 2007).

GRAS status is not an inherent property of a substance, but must be assessed in the context of the intended conditions of use of the substance (section 201(s) of the Act [21 U.S.C. § 321(s)]). The assessment includes a consideration of the population that will consume the substance (21 CFR 170.30(b); section 409(b) of the Act [21 U.S.C. § 348(b)]). Therefore, the scientific data and information that support a GRAS determination must consider the conditions under which the substance is safe for the use for which it is marketed. Reports in the scientific literature have raised concerns regarding the formulation and packaging of pre-mixed products containing added caffeine and alcohol. For example, these products, presented as fruity soft drinks in colorful single-serving packages, seemingly target the young adult user. Furthermore, the marketing of the caffeinated versions of this class of

alcoholic beverage appears to be specifically directed to young adults (Bonnie and O'Connell, 2004). FDA is concerned that the young adults to whom these pre-mixed, added caffeine and alcohol products are marketed are especially vulnerable to the adverse behavioral effects associated with consuming caffeine added to alcohol, a concern reflected in the publicly available literature (O'Brien et al., 2008; Simon and Mosher, 2007).

It is FDA's view that the caffeine content of your beverage could result in central nervous system effects if a consumer drank one or more containers of your product. Therefore, FDA believes that the consumption of your product, "Four Loko," may result in adverse behavioral outcomes because the caffeine is likely to counteract some, but not all, of the adverse effects of alcohol. The agency is unaware of any data that address the complex, potentially hazardous behaviors that have been identified in the scientific literature as associated with these beverages or that otherwise alleviate our concerns about the effects of consuming these pre-mixed caffeine and alcohol beverages. Moreover, FDA is not aware of any publicly available data to establish affirmatively safe conditions of use for caffeine added directly to alcoholic beverages and packaged in a combined form.

As noted, FDA has reviewed the information in your GRAS Notice as well as other publically available information and continues to have safety concerns about your caffeinated alcoholic beverage product. In considering the totality of the information presented in the GRAS Notice, FDA notes that the GRAS Notice did not cite any scientific literature of which the agency was not already aware.[6] We note that in an e-mail dated August 10, 2010, the Office of Food Additive Safety did request three references cited within your GRAS Notice. We had been aware of these references but due to their age, had not been able to locate them.[7] Furthermore, we wish to comment generally on two lines of argument presented in your GRAS Notice.

First, your GRAS Notice relies primarily upon safety studies of caffeine alone (i.e., not in the presence of alcohol) to support your view that caffeine is safe under the relevant conditions of

use (that is, in combination with alcohol). Importantly, however, the current scientific literature, which we cite above, establishes that significant safety concerns are raised by the co-consumption of caffeine and alcohol. Accordingly, data and information addressing the safety of caffeine alone are not sufficient to establish the safety, and the general recognition of the safety, of beverages that combine caffeine with alcohol.

Second, we note that one section of your GRAS Notice reviews some of the studies that have reported the adverse behavioral effects elicited by the co-consumption of caffeine and alcohol and identifies purported deficiencies in the design and interpretation of these studies. Even if certain studies in the scientific literature have limitations due to their design or the interpretation of their results, the peer-reviewed literature as a whole is sufficient to raise, among qualified experts, safety concerns about alcoholic beverages to which caffeine has been directly added. Similarly, even if the results from no single study are sufficiently comprehensive to characterize fully the potential responses to beverages containing caffeine added to alcohol, these studies are collectively sufficient to raise concerns about consumption of this combination and to support the conclusion that more research is required. Furthermore, FDA is not aware of any reports in the literature that refute the association between the co-consumption of alcohol and caffeine and adverse behavioral results or that otherwise affirmatively establish the safety of these beverages. Indeed, our review of this literature, as well as certain related studies in animals, shows that there are currently no studies or other information that refute the safety concerns or otherwise affirmatively establish the safety of caffeine directly added to alcoholic beverages. Therefore, we are not aware of a sufficient basis to support a conclusion that caffeine, when directly added to alcohol to form a single beverage, is generally recognized as safe.

The agency is aware that your company received a Certification/Exemption of Label/Bottle Approval (COLA) from the Alcohol and Tobacco Tax and Trade Bureau (TTB) and that, as part of your application for the COLA, you informed TTB that your product would contain caffeine. A

COLA does not constitute a food additive petition approval, a statement regarding GRAS status, or a prior sanction, and you are obligated to abide by the provisions of the Federal Food, Drug, and Cosmetic Act.

In light of the safety concerns identified above, the use of added caffeine in the alcoholic beverage product "Four Loko" does not satisfy the criteria for GRAS status outlined above. Further, FDA is aware of no other exemption from the food additive definition that would apply to caffeine when used as an ingredient in an alcoholic beverage product. Therefore, caffeine as used in your product is a food additive under section 201(s) of the Act [21 U.S.C. § 321(s)] and is subject to the provisions of section 409 of the Act [21 U.S.C. § 348]. Under the latter, a food additive is required to be approved by FDA for its proposed conditions of use prior to marketing. Because caffeine is not an approved food additive for its use in your product, "Four Loko," this product is adulterated within the meaning of section 402(a)(2)(C) of the Act [21 U.S.C. § 342 (a)(2)(C)].

You should take prompt action to correct this violation and prevent its recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions and prosecutions against manufacturers and distributors of those products.~

Please advise this office in writing within fifteen (15) days from your receipt of this letter as to the specific steps you have taken to correct the violation identified above and to assure that similar violations do not occur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections within the 15 days, please explain the reason for your delay and the date by which each such item will be corrected and documented.

Please send your reply to Seyra Hammond, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-605), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

/s/

Joann M. Givens
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition,

cc: Food and Drug Administration Chicago District Office

Questions to Ponder About *FDA v. Phusion*

A. Before Phusion came along, professional bartenders and amateur partiers alike mixed 80-proof liquor or even 200-proof grain alcohol with energy drinks containing caffeine. And even before energy drinks came on the scene, it was common to mix caffeine and alcohol. The popularity of one particular combination during the World War II era is memorialized in the Andrews Sisters' song, "Rum & Coca-Cola." Should those historical facts matter to the interpretation of 21 CFR 170.3?

B. Should it matter under 21 CFR 170.3 that the alleged harmful effect of a food additive is behaviorally mediated? In other words, does it matter that a food additive is not directly physically dangerous, but instead is risky solely because of its link with behavior and the choices people make?

C. Should it matter that Phusion's products are "presented as fruity soft drinks in colorful single-serving packages" and that they "seemingly target the young adult user"? Do either of these facts bear on whether the drinks are "adulterated"?

D. Based on what you read, how would you characterize Phusion's situation in terms of tort liability? Apparently, at the time the letter was written, the prospect of tort liability had not caused Phusion to stop selling caffeinated alcohol drinks. Why not?

E. Did Phusion's prospective tort liability change as a result of this letter and the fact that Phusion received it? What impact could the letter and its analysis have in a tort lawsuit against Phusion? Put yourself in the position of Phusion's general counsel: After receipt of this letter, would you advise Phusion to stop selling caffeinated

alcoholic beverages? To what extent does tort law play a role in your analysis?

Case: *FTC v. Phusion Products LLC*

On the same day that the FDA sent its letter, the FTC wrote to Phusion to add its concern that the marketing of Four Loko might constitute a violation of the broad provisions of 15 U.S.C. § 45(a), which provides: "(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful. (2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations … from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce."

FTC v. Phusion Products LLC

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Consumer Protection
Division of Advertising Practices

November 17, 2010

Via Electronic Mail
Andrew J. Strenio, Jr.
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005

RE: NOTICE OF POTENTIALLY ILLEGAL MARKETING
OF CAFFEINATED ALCOHOL PRODUCTS

Dear Mr. Strenio:

Your client, Phusion Products LLC ("Phusion"), markets and sells Four Loko and Four Maxed, alcohol beverages containing caffeine directly added as a separate ingredient. Four Loko, a carbonated malt beverage that comes in several fruity flavors, is sold in 23.5 fluid ounce cans containing 11% to 13% alcohol by volume (depending on the state), plus added caffeine, taurine, and guarana. Thus, one can of this product contains the same alcohol content as four regular or five light beers. Four Maxed, also a carbonated malt beverage with added caffeine that comes in fruity flavors, is sold in 16 fluid ounce cans containing 10% alcohol by volume (equivalent to about three regular beers). These products sell for less than $3.00 a can. This letter serves to advise Phusion that its marketing and sale of Four Loko and Four Maxed may constitute an unfair or deceptive act or practice in violation of the Federal Trade Commission Act, 15 U.S.C. § 45. The Federal Trade Commission enforces the Federal Trade Commission Act, which, among other things, prohibits unfair or deceptive acts or practices in or affecting commerce, *id.*, and the false advertising of food, drugs, devices, services, or cosmetics, 15 U.S.C. § 52. The Food and Drug Administration is responsible, among other things, for ensuring that any food, drug, device, or cosmetic is not adulterated, misbranded, or otherwise improperly labeled. See generally Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.*

Consumer safety is among the highest priorities of the Federal Trade Commission ("FTC"). Safety concerns have, in the past, contributed to the Commission's decision to take action against alcohol marketers. We are aware of a number of recent incidents suggesting that alcohol containing added caffeine may present unusual risks to health and safety. Over the past several months, consumers in at least four states have been hospitalized following consumption of caffeinated alcohol. These incidents suggest that consumers, particularly young adults, may not fully appreciate the potential effects of consuming caffeinated alcohol beverages such as Four Loko and Four Maxed.

We have further been advised that the Food and Drug Administration ("FDA") has warned you that caffeine, as used in your product, Four Loko, is an "unsafe food additive" under the Federal Food, Drug, and Cosmetic Act. As a result, this product is deemed adulterated.

The FDA's warning that caffeine is an "unsafe food additive," as used in Four Loko, is a relevant consideration in the FTC's analysis of whether the marketing of caffeinated alcohol products such as Four Loko and Four Maxed is deceptive or unfair under the Federal Trade Commission Act. In the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy.

The FTC staff therefore strongly urges you to take swift and appropriate steps to protect consumers. Even in the absence of express safety claims, the very act of offering goods for sale creates an implied representation that the goods are reasonably fit for their intended uses and free of gross safety hazards. In addition, the non-disclosure of rare but serious safety risks may constitute an unfair practice.

Please notify Janet M. Evans~ and Carolyn L. Hann~ in writing, within 15 days, of the specific actions you have taken to address our concerns. You may contact Ms. Evans and Ms. Hann by email or, alternatively, by mail~.

Very truly yours,

/s/

Mary K. Engle
Associate Director
Division of Advertising Practices

Historical Note on Phusion and Four Loko

As it turns out, Phusion did not fight the FDA. On the same date as the letters, November 17, 2010, Phusion announced that it would voluntarily remove caffeine from its formula for Four Loko.

Just five days later, Kansas's Department of Alcoholic Beverage Control used its administrative power to ban Four Loko within the state. And the next month, special agents of the Virginia Department of Alcoholic Beverage Control conducted a sting operation to arrest a man for selling alcoholic beverages without a license. The man used Craigslist to unwittingly meet an undercover officer to sell eight cans of Four Loko for $80. The Kansas and Virginia experiences illustrate how state administrative agencies often have overlapping regulatory jurisdiction with federal authorities.

Problem: ***Boogie Woogie Bugle Boy Beverages***

Suppose that after Phusion removed the caffeine from Four Loko, a new group of entrepreneurs see an opening in the market. They form Company B LLC and begin marketing a bottled drink called Boogie Woogie Bugle Boy Rum and Cola. To advertise, they produce a videos featuring mash-ups of the Andrew Sisters' recordings of "Boogie Woogie Bugle Boy" and "Rum & Coca-Cola," both originally recorded in the 1940s. The company focus-group tests the videos, the product packaging, and the product itself, exclusively with persons aged 70 or older, and it finds that all elements work well with this demographic. Shortly after the drink hits the market, however, a social media buzz – entirely unorchestrated by Company B – causes sales to skyrocket among persons in the 21- to 24-year-old age range. This demographic soon accounts for 87% of sales. This effect was not unexpected. The entrepreneurs were hoping for a kind of retro-reverse coolness effect to happen, since they were familiar with similar phenomena in recent years concerning brands of clothing and deodorant. Does Company B have anything to worry about in terms of FDA or FTC regulation?