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On a sunny summer afternoon eight years ago, Dan Wilson and Susan Knapp exchanged wedding vows on a hilltop in their upstate New York apple orchard. In the apple barn down through the trees, we toasted them with their own cider. We drank up, despite knowing that the Food and Drug Administration had proposed making it a crime for them to sell it.

The FDA had said that the unpasteurized juice of apples is dangerous because of the possible presence of E. Coli bacteria. That is not quite true, as many in the wedding company could explain. We also knew that Dan and Susan were worrying that an FDA mandate to pasteurize would turn this orchard upon which Dan was reared into a losing proposition. A few nights before the wedding, sitting at our kitchen table, he said, "I can imagine the day when my closest relation to growing apples will be buying them in the supermarket." Susan nodded. That would be a tragedy: they are a focus of our rural society. Their quitting farming would leave a hole bigger than a barn.

The pall that the FDA cast on their wedding was but one scene in an apple cider saga that changed how I think about regulation. As a Natural Resources Defense Council litigator in the 1970s, I had focused on getting the federal agencies to protect public health. The complaints about the difficulties of compliance mattered to me chiefly as an obstacle to that goal. I still want health protected, but, as a friend of Dan and Susan, I learned that regulation, even when well-intentioned, sometimes quite unnecessarily discourages initiative and creativity.

The FDA had gotten involved with cider two years before the wedding, when an infant in California had died because of E. Coli contamination in bottled fruit juice. The juice had come from Odwalla, at that time a large West Coast company, but the FDA began to consider regulating all producers of fruit juices, down to small cider makers such as Dan and Susan.

E. Coli can get into cider because deer and mice, which are among its carriers, have a taste for apples. One response is to pasteurize the juice, which also brings the commercial benefit of longer shelf life. Odwalla, however, had taken pride in not pasteurizing; it advertised its products as tasting better because they were only minimally processed. After the E. Coli outbreak, it installed equipment that pasteurizes by heating and cooling the juice in such a flash that the taste

is not much affected.

The Apple Processors Association, dominated by large companies, urged the FDA to require that all juice be pasteurized. That would have been ruinous for small cider producers. At that time, equipment that pasteurizes in a flash cost upward of $70,000. Even budget pasteurizers cost $25,000, but they are prone to cook the taste out of cider and require extra employees to operate. Cider that tasted like canned apple juice, plus higher operating costs, spelled bankruptcy to Dan and Susan. Not so for the members of the Apple Processors Association.

They already pasteurized, and stood to pick up the sales of the small producers driven out of business.

In any event, the FDA proposed to decree that juice be put through a sanitizing process that would cut bacteria levels at least 100,000-fold. Culling the apples and then washing them would probably have accomplished that, but the rule required that the cut take place in one step. The only way to do that was pasteurization. While still pondering this proposal, the FDA promulgated another rule that the Apple Processors Association wanted. Any unpasteurized juice must carry a label with this chilling warning: this product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems. This was three days before Dan and Susan's wedding.

Many customers at their cider barn threatened to stop buying their cider if it were pasteurized. They liked its fresh taste and were unconcerned about E. Coli, their forebears having drunk cider from this orchard for a century without apparent incident. (So, too, do Europeans like the taste of real Brie, Camembert, and other young cheeses made from unpasteurized milk. They accept the small risk from E. Coli and other pathogens--a risk that has prompted the FDA to allow only ersatz versions into the United States.) By contrast, the scary label would have spooked consumers who bought the cider at a few supermarkets in a nearby city; these stores stopped carrying Dan and Susan's cider.

Going to the annual meeting of the New York State orchard owners the following winter, Dan was dejected, but he met someone there who cheered him up. Phillip Hartman, a 52-year-old engineer, was displaying the prototype of a machine that he claimed would sanitize cider without hurting the taste, yet could be sold for $12,000 and would require no extra employees to operate. That was his hope--but only a hope. He had neither approval from the FDA nor even a company to build the machines. Phil, whose full-time job was in the computer industry, had been trying to help a fellow employee, with a friend in the same pickle as Dan and Susan, figure out how to use ultraviolet light to sanitize cider. The problem was that, though ultraviolet can sanitize water, the cloudiness of cider prevents the light from penetrating deeply enough. Phil, whose engineering specialty is creating the thin films on computer wafer board, hit upon a way to make the cider run by the light source in a film so thin, 30/1000 of an inch, that the ultraviolet would sanitize every drop.

By the fall of 1997, Phil had an ultraviolet device ready for bench testing, but he needed a biologist to confirm that it killed the E. Coli. Randy Worobo, who had just joined the faculty of Cornell University's Agricultural Experimental Station, agreed to help. His test found that the device did cut the bacteria 100,000-fold, as required. Phil elaborated this device into the prototype that he brought to the orchard owners' annual meeting.

Although Phil still had many hurdles to overcome, the orchard owners got the sense that, as Dan put it, "this guy would do everything he could to make things right." The opinion that counted most was that of Russell French, a distributor of orchard equipment, who agreed to do the selling. He was running a risk. If Hartman's machines failed to work, or if the FDA refused to sanction them, French would alienate his customers and might even face lawsuits from people who got sick after drinking cider. Encouraged, Phil quit his job and set up a company to make cider-sanitizing machines.

Dan and Susan placed one of the first orders, linking their future to Phil's ability to deliver machines that satisfied the FDA. Their machine arrived in time for the 1999 cider season, but the early equipment had glitches. Phil would get phone calls from orchard owners desperate because a balky machine stood between a barn full of perishable apples and

customers with cash. Phil would respond by getting into his van and driving through the night from his home in western New York to orchards as far away as Vermont, Virginia, or Michigan. Driving was his only option: a paraplegic since his teens, he could not negotiate an airport with his wheelchair, tools, and spare parts.

Taking the glitches out of the machines proved easier than winning regulatory approval. One hurdle was the FDA's rule requiring that cider be either pasteurized or labeled as dangerous. Phil's machines, even though they did reduce E. Coli by 100,000-fold and in one step, did not pasteurize, and the FDA had not decided whether their use permitted cider makers to omit the drink-this-at-your-own-peril label.

While the FDA dithered, cider makers across the country bought pasteurizers or went out of business, because they feared taking a chance on Phil Hartman's machine. Not in New York State, however. In the words of its chief food-safety regulator, Joseph Corby, "We told the cider producers, ?We license you and we approve Hartman's machine. The FDA has no reasonable basis to withhold its approval, and, if it does, there will be a battle.[#x2dc] As a result, we got a lot of nasty calls from pasteurizer manufacturers." It was not until late 2001 that the FDA decided that cider made with Phil's machine did not have to carry the warning label.

Corby's solicitude for New York cider makers saved dozens of them from going under.

From 1997 to 2000, while the FDA rules were driving producers out of business elsewhere, New York's cider producers multiplied. By contrast, in Vermont, just a few miles away from Dan and Susan's orchard, fully 60 percent of the cider producers ceased operation during the same period. Overall, in states like New York, which supported sanitizing by ultraviolet, the number of producers stayed steady; in states that left their producers to the FDA, the number of producers declined 38 percent.

Phil ran into another, more ominous FDA problem. The agency had long had a rule limiting the exposure of food to ultraviolet light, not because it had evidence that it was dangerous but because it lacked definitive evidence to the contrary. It had put an exception into that rule for a company whose machine used higher levels of ultraviolet than did Phil's for sanitizing the surface of fatty foods like potato chips, but the exception did not cover the use of ultraviolet on fruit juice. FDA officials told Phil to emulate that company's successful application, and he would get his exception. He did as told, but a year later the FDA wrote that his application could not be considered without more information. And then, alarmingly, it warned that, until he got an exception, the FDA would enforce its anti-ultraviolet rule by shutting down any cider maker using his machines. His customers--including Dan and Susan, now his friends--would be out of business.

Phil decided that he needed a lawyer quick and found one who had worked for the FDA. He took the $10,000 retainer out of his savings. The lawyer filed a new application for an exception to the ultraviolet rule. The FDA eventually summoned Phil to a meeting at its Washington, D.C. headquarters, where an official read him a prepared statement that his new application was faulty. Officials told him, however, that the bottler that made Naked Juice, at that time a major West Coast brand like Odwalla, had filed its own application to use ultraviolet on fruit juice. The officials advised Phil not to apply again, because that would delay Naked Juice getting an exception--and that exception would cover him.

The FDA later did approve the Naked Juice application, but in a way that didn't legalize Dan and Susan's machine. While Phil had elegantly solved the problem of getting ultraviolet to penetrate cloudy cider by running it past the light in an ultra-thin, smooth stream, Naked Juice had done so with brute force--by applying a much larger dose of ultraviolet to a thick stream. Critical to the functioning of the Naked Juice machines was that the stream be turbulent, to bring all the cider close to the ultraviolet light at some point. Both kinds of machine cleaned the cider, but the exception that the FDA granted to Naked Juice required cider-sanitizing machines to have a turbulent flow. The effect was to outlaw the machine that Phil had sold Dan and Susan, even though it was just as good at sanitizing the cider and, because of its superior design, used far less of the ultraviolet that the FDA had viewed as risky.

Fortunately, Phil had a way of altering his machines to meet the FDA's turbulent-flow proviso, and he drove hither and yon to retrofit them. He remained bothered, however, by the FDA's action. The agency put him through the wringer, on the theory that ultraviolet might be dangerous, but in the end it put no limit on ultraviolet exposure. It required a particular technique (turbulent flow) rather than a good outcome (safe cider), thereby limiting the ways in which he might use his expertise in thin-film technology to produce a still-better machine. The FDA's procedural rules did, however, offer him recourse: to file a formal objection. That he did, with Cornell biologist Randy Worobo's help. It was lucid and well documented. The FDA never responded.

Phil is still making his machines, with the help of his niece and three other young, part-time employees on rented floor space in someone else's factory. His office is in his home. Now that he's sold 120 machines, the market is close to saturated. He does not know what he will do next, but when he quit his job to start this business, he knew that his income would be lower and less secure. Is he glad that he did it? "Oh hell yes. I have enjoyed myself immensely. I enjoy the cider makers. I enjoy the traveling. I enjoy the young people." He has since taken up scuba diving, with the help of his niece.

Phil could not have succeeded without Worobo, who diverted time from conventional academic work and made enemies potentially dangerous to a then-untenured professor. As he recalls, "On Good Friday in 1999, two salesmen from a pasteurizing-machine company came into my office and screamed and hollered at me for four hours. They said they didn't like competing with Cornell." Why did he do it--and for free? "Phil Hartman is a brilliant engineer, and I enjoy working with him. I also feel compassion for the cider makers. I am from a farming background myself. I know what it was like when my parents got screwed." On account of Phil's success, Dan and Susan can still make cider.

Dan and Susan never had any quarrel with the FDA's aim of reducing exposure to E. Coli. Before the agency stepped in, they culled the fruit to get rid of any that was nibbled or damaged and washed it before putting it into the press. Parents do no more in feeding apples they pick to their children. The FDA itself now finds such techniques an acceptable alternative to pasteurization for orange juice. Apples are different from oranges, and Dan and Susan are glad to have purchased Phil's machine. It gives them peace of mind.

The FDA could, however, have protected us to the same degree--a 100,000-fold reduction in E. Coli in apple cider--but with less harm to those regulated, if it had not long insisted that this reduction had to be achieved through pasteurization, had not required that the reduction be done in one step, and had not decreed that there was only one acceptable way to employ ultraviolet to achieve that one-step reduction. By specifying the means to achieve a sensible regulatory end, the agency unnecessarily put hundreds of cider producers out of business and subjected others to years of anxiety.

Regulators should avoid dictating the means to achieve an objective when it would be enough to dictate the objective itself. As Adam Smith and Friedrich Hayek taught, the world is too complicated for officials to know what will work best. Local innovators like Phil Hartman, experimenting and tinkering, drawing on their store of experience and ingenuity, are much better suited to come up with unexpected solutions that will increase the general welfare and prosperity.

The FDA's world is especially complicated. It regulates the giants of the drug, food, and cosmetic industries, so it's no wonder that, from the perspective of its Washington headquarters, small-scale cider producers are invisible. The world is somewhat less complicated at the state level. From Joe Corby's vantage point in the Department of Agriculture and Markets in Albany, New York, Empire State cider makers were not only visible but also important. According to Cornell's Worobo, "Usually, the FDA acts first, and the state agencies follow, but some state regulators stuck their necks out this time, because lots of local businesses were in trouble. These little businesses were beneath the notice of the FDA."

Dan and Susan also come under Environmental Protection Agency regulation. Its world is even more complicated than that of the FDA. Congress requires it to regulate in exacting detail thousands of pollutants coming from millions of

sources. According to former Environmental Defense Fund chairman Richard Stewart, now a New York University law professor, the EPA's regulation "has grown to the point where it amounts to nothing less than a massive effort at Soviet-style planning of the economy to achieve environmental goals."

But for the vast majority of pollution sources, the impact is mainly local, and how to regulate it turns on local circumstances. So the EPA is supposed to make a huge number of decisions that should be locale-dependent, cramming a flood of controversial choices through the constricted funnel of a single national regulatory system. That is why, under Democratic and Republican presidents alike, it is woefully behind statutory schedule in promulgating new regulations and revising old ones. And in its rush to get the job done, it issues regulations designed to fit hypothetical, standardized firms and farms rather than the multiplicity of real ones.

Even when I was still an environmental litigator, I understood that the EPA could make the world much less complicated by giving polluters more latitude on how to achieve environmental objectives and by devolving the regulation of most of them to the states, excepting only the small number that contribute substantially to interstate pollution. What I did not understand then, but came to understand by witnessing Dan and Susan's regulatory travails, is that making a federal case of intrastate pollution casts yet another pall on individual initiative and creativity.

So immense is the EPA mandate that not only can the agency not understand those it regulates, but it cannot effectively communicate its regulatory requirements, even to large businesses. As an environmental law treatise acknowledges, "[I]t is virtually impossible for a major company (or government facility) to be in complete compliance with all regulatory requirements. [And yet] virtually every instance of noncompliance can be readily translated into a [criminal] violation." When asked in a survey to explain why there is so much noncompliance with environmental laws, environmental attorneys identified the most important factors to be not the cost of compliance, but the "sheer number of regulations," "complexity of regulations," "too many different and conflicting requirements," and "keeping track of changes in regulations."

To decode this complexity, giant corporations put environmental law experts on their payrolls and retain law firms staffed with top environmental specialists. A smaller company can't afford such legal overhead, but even a firm operating a single plant must grapple with almost as much regulatory complexity as a corporate behemoth running 50 plants. Not only do small firms have a tougher time than large ones decoding regulatory requirements; they also face much higher compliance costs: with the EPA, that amounts to $3,328 per employee for firms with fewer than 20 employees, versus $717 for firms with more than 500 employees.

But, of course, the smallest enterprises can't afford to hire any expert help at all. Dan and Susan now worry about the EPA, even though they are committed environmentalists: she had worked for the California Coastal Commission; he chairs the local natural history museum and wildlife sanctuary. They can manage their orchard without causing water pollution but not without pesticides. The EPA, in regulating farmers' use of pesticides, must not only ensure food safety but must also write its regulations so that they leave farmers with some way to protect their crops. In this part of its task, the EPA is much more apt to take account of the largest blocs of farms, such as big corn or soybean spreads in the Midwest, than to pay attention to niche operations like Dan and Susan's. They have a micro-farm in a microclimate, where they face pests unlike those faced by apple growers elsewhere in the country. They understandably fear that the EPA might, in some national administrative hiccup, inadvertently leave them with no way to stop some pest that is killing their trees. To decipher their regulatory fate, Dan has spent hours on the EPA's website but comes away frustrated. His calls to the EPA's help line leave him with "the impression that their computer screens showed the same materials as mine, and they knew less than I did."

It is difficult enough to begin or expand a tiny business without the risk of unwittingly stepping on regulatory land mines. As Phil Hartman's experience with the FDA suggests, a regulatory problem that would have been a minor irritation to a big firm can topple a start-up. Moreover, large corporations can send their teams of lawyers and lobbyists to Washington to impress their concerns on federal regulators. Little firms and farms can't.

Discouraged by his regulatory prospects with the EPA, Dan e-mailed me: "If I could characterize my outlook to the whole process, it would be variations on the theme of resignation. I am frustrated sometimes by what seems to be EPA's monumental lack of understanding about the complexities that are inherent in running a little farm like ours. But I can't muster much energy for this fight. I can't do everything else I need to do in a day with the weight of concern about EPA on my shoulders." Such a regulatory regime prompts people who want to run their own enterprise to work for others, and for smaller businesses to be acquired by larger ones. Odwalla is now a unit of Coca-Cola, and Naked Juice is a unit of Chiquita Brands.

Dan and Susan could earn more working for a large corporation, but they love being their own bosses and having scope for creativity and initiative. They hope to enlarge that scope by making some of their sweet cider into hard ciders and ice wines. The value added would, if all works well, let them still make a living, even if the EPA drives them out of growing the apples themselves. Of course, making alcoholic beverages requires a permit from a federal agency--no surprise there. They estimate the paperwork for the permit application took about 150 hours of late nights, after days and evenings caring for trees and children. But, according to Susan, "We knew what to expect, and we got the permit. It was a piece of cake compared with the FDA and the EPA."

Agencies like the FDA and the EPA, with the power to regulate means as well as ends, and with jurisdiction over even the most local problems, engage in backdoor central planning. They stifle individual initiative and creativity and herd increasing numbers of would-be entrepreneurs into working for large bureaucratic corporations, which are more capable than smaller, more dynamic firms of dealing with Washington bureaucrats. The upshot is that our work is less enjoyable, because it is directed from on high. It is also less fruitful.

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