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Federal White Collar Crime:

Six Case Studies Drawn from Ongoing Prosecutions to Protect Public Health, Worker and Consumer Safety, and the Environment

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November 2015

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The Campaign Against 'Overcriminalization'

The Heritage Foundation, the Koch brothers, and other allies have pressed members of Congress to deal with the "overcriminalization" of federal law enforcement by enacting changes in statutory *mens rea* standards. These radical revisions would affect white collar criminal prosecutions for everything from mail, wire, and securities fraud to adulterated food and drugs, mine safety, and automobile defects.

The Heritage Foundation and the Koch brothers argue that Congress has put too many laws on the books without specifying whether a defendant must have a "guilty mind" (*mens rea*) in order to be convicted. They add that federal agencies have created thousands of so-called "regulatory violations" that trigger criminal liability and that these provisions are so hyper-technical that no reasonable person could understand what they mean, much less apply them to ordinary conduct. The Heritage Foundation has published a booklet entitled *U.S.A. vs. You* telling the sad stories of average citizens victimized by venal prosecutors for doing their jobs, helping wildlife, caring for children, and engaging in a variety of other useful tasks.[1]

This paper tells a very different story about the people and corporations the Department of Justice (DOJ) has prosecuted or investigated for white collar crimes in the last several years. Cumulatively, these cases involve the death of hundreds of people, with many more made gravely ill, and include the worst environmental disaster in the nation's history.

1. The 2005 BP Texas City refinery explosion that killed 15[2]
2. the 2010 BP Deepwater Horizon explosion that killed eleven and released 210 million gallons of crude oil into the Gulf of Mexico, causing irrevocable environmental damage
3. The 2010 collapse of Massey Energy's Upper Big Branch mine that took 29 lives
4. The Peanut Corporation's 2008 shipment of peanut paste contaminated with salmonella with the result that 9 people died
5. The New England Compounding Center's 2012 sale of 17,000 vials of steroid injections tainted by fungal meningitis with the result that 64 patients died and 741 contracted meningitis
6. The installation of a cheat device in 11 million Volkswagen cars

These narratives illustrate that corporate managers involved in these incidents acted with recklessness regarding the safety of their workers, their customers, and the environment and

were willfully blind to what the law required. In most cases, regulatory authorities warned them repeatedly that their conduct was illegal, and they were approached multiple times by employees and outside experts gravely concerned about the intolerable risks they were taking.

Much of the material contained in this paper appeared in my 2014 book *Why Not Jail? Industrial Catastrophes, Corporate Malfeasance, and Government Inaction* (Cambridge University Press 2014) and an article I published in the Harvard Journal of Law & Policy in 2015 entitled *(Still) "Unsafe at Any Speed": Why Not Jail for Auto Executives?*, 9 HARV. L. & POL'CY Rev. 443 (2015).

Despite the isolated anecdotes advanced by the Heritage Foundation and its allies, the simple truth is that federal and state prosecutors are overly hesitant to bring white collar cases. Whether these prosecutors are afraid of losing, worried about matching wits with the big law firms, or lack the political will to proceed, the end result is the same: People die for preventable reasons every day in America and the vast majority of corporate managers responsible for such episodes escape even a hint of criminal charges. We don't have a white collar over-criminalization problem in this country. We have an under-criminalization problem.

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The Texas City Refinery

> It was typical of them to experience a fire every week, on average. A fire every week is a warning sign that something is critically wrong at the facility.
>
> Mike Sawyer, independent process safety consultant for BP[3]

The 52,000 Gallon Geyser

On March 23, 2005, a massive explosion at BP's Texas City refinery killed 15 people and injured 200, 170 seriously. The blast was so forceful that it damaged houses three-quarters of a mile from the plant. Emergency responders ordered 43,000 people in the neighborhoods surrounding the 1,200 acre site (an area covering two square miles) to "shelter in place," meaning that they were directed to go into their homes, seal windows and doors, and remain inside until the all-clear. The incident is considered one of the worst industrial accidents in American history.

The explosion originated in the "isom," one of 30 separate chemical process areas within the plant's gated boundaries. (Isom is short for isomerization, the process by which hydrocarbons are transformed into different substances containing the same atoms in different configurations.) The unit featured a 170-foot "raffinate splitter tower" used to separate petroleum into petrochemicals such as toluene, xylene, and benzene. The isom was in start-up at the time of the accident, meaning that it was being put back into service after shutting down for maintenance over a period of several weeks. Start-up is well known in the oil and petrochemical industries as a particularly dangerous phase of operation for any equipment handling volatile and toxic chemicals, requiring punctilious adherence to safety protocols before and during implementation.

To operate safely, a raffinate splitter tower of this design must never be filled with unfinished petroleum beyond a six to nine foot level. But in this instance, badly trained and unsupervised workers kept pumping flammable liquid hydrocarbons into the tower for over three hours without opening the equipment's outflow valve. Incredibly, the plant's procedures for operating the isom were so flawed that these men were under the impression that they were not allowed to relieve pressure by opening the valve. Worse, they did not realize that by overfilling the tower to a level of 155 feet without draining it simultaneously through the outflow valve, they were in effect making an industrial bomb.

As the level rose within the isom to the dangerous height of 155 feet, liquid and gas poured out into emergency overflow piping attached to the top of the tower, traveling through the piping across a distance of several hundreds of feet and into a "blowdown drum" – a large barrel-shaped container with an attached vent stack that opened into the ambient air. The drum filled to capacity triggering three pressure relief valves that opened automatically for six minutes, discharging a "geyser-like" plume of 52,000 gallons of volatile liquid and gas over the unit. The plume drifted inexorably toward the ground. At 1:20 p.m., an idling truck parked against plant rules near the isom unit backfired, producing a spark that ignited the plume, producing a massive and powerful explosion.

Most of those killed were working in two trailers located 140 and 126 feet from the isom unit and used for office space, in yet another blatant violation of a long-standing safety rule that such facilities should not be closer than 350 feet from potentially hazardous units at the plant, especially during start-up.

Independent investigators sent to the plant after the blast discovered that because BP had a policy requiring workers involved in shutdown and start-up to work every day until both missions were accomplished, isom crew members had worked twelve-hour shifts for 29 consecutive days. Compounding these fraught working conditions, during the vital few hours leading up to the explosion, a line supervisor left the site to attend to a family emergency, and no one was available to replace him.

The Trail Back to BP's London Headquarters

At the time of the isom explosion, the Texas City refinery was the third largest in the country, producing 11 million gallons of gasoline a day, or about 3 percent of the country's total consumption. It generated profits in 2004 of $900 million, a remarkable achievement considering its acute state of disrepair. Located 45 miles south of Houston, on the coast of the Gulf of Mexico and built in 1934, the refinery was already well past its heyday when BP acquired it by buying Amoco in 1999. The physical plant had deteriorated to the point that first-time visitors, even those accustomed to the grit of the refinery business, were taken aback.

BP executives considered offloading Texas City and its lurking liability risks to another oil company. But a deal never materialized and Texas City got swept up in upper management's other obsession – cutting costs. Company-wide, BP managers wanted to boost the return on capital from seven percent in 1999 to 20 percent in 2005. Ultimately, over a period beginning in 1992, when Amoco still ran the plant, to the time of the explosion, capital spending was reduced by 84 percent and maintenance was cut by 41 percent. No cut was too small to be considered. Dozens of maintenance workers were fired to save $1 million, purchases of safety shoes were reduced to save $50,000, and safety awards were cut to save $75,000.

In 2002, Don Parus, a former Amoco executive with two decades of experience in the oil industry, joined the management structure that supervised Texas City and BP's other holdings in the state. In 2004, he became the refinery's "Business Unit Leader" (BUL), a euphemism for plant manager. Stunned by the appearance of the physical plant, he commissioned a study of the depth and severity of maintenance problems, discovering to his further dismay serious reliability issues, including faulty instruments and broken equipment. The report concluded that Texas City needed a major infusion of funding for corrective maintenance. Parus requested $235 million from corporate headquarters in America and London.

Some senior executives apparently agreed with Parus, and he thought additional funding would be forthcoming. But orders soon came down from London mandating more cuts because Texas City was simply not profitable enough. Why, said senior managers, should Texas City provide 15 percent of refinery profits but consume 18 percent of the corporation's safety budget for that sector?

Texas City became more and dangerous. Incidents involving accidental spills and fugitive air emissions increased from 399 in 2002 to 607 in 2004. A furnace pipe ruptured in March 2004, causing a fire that cost BP $30 million. In September 2004, a pipe flange was mistakenly opened by three workers and the pipe burst, killing two of the men and severely burning the third with a mixture of boiling water and steam. Parus asked for the plant's historic fatality record and was once again shocked to discover that 23 men had died in a thirty-year period.

After the explosion, BP hired a blue-ribbon commission headed by former Secretary of State James A. Baker III to evaluate what went wrong. Its 2007 report did not equivocate, concluding that the accident was attributable to a culture that allowed crucial components of the physical plant to "run to failure" and penalized workers for expressing safety concerns. BP also assembled a team of its own senior executives to evaluate management failures at the refinery. Two "confidential" reports prepared "for internal use only" focused on the culpability of five senior executives, John Manzoni, the BP Chief Executive for refining, Michael Hoffman, group vice president for U.S. refining and Parus. BP investigators concluded that Hoffman and Parus, who did not get along, had promoted a "fortress mentality," discouraged underlings from reporting problems, and neglected to supervise or evaluate lower-level managers.

Other investigations emphasized the impact of relentless cost-cutting directives. For example, the isom, installed five decades earlier, did not have a "flare" (constant flame) at the top of the blowdown drum to burn off emissions before they could ignite at ground level. Flares had been standard equipment on blowdown drums for many years. In 1999, BP managers had considered retrofitting the drum to incorporate such equipment, which would have cost approximately $2 million, but decided the change was too expensive. They also considered the less expensive alternative of hooking the isom up to a nearby blowdown drum that did have a flare that was located nearby and was used with other equipment that did have a flare, at a cost of $150,000, but they decided that even this measure was too expensive. An internal company email written at the time said "Capital expenditure is very tight. Bank $150k in savings now."

Increasingly worried about a series of accidents at the plant, including several fatalities, plant manager Parus commissioned a consulting firm named Telos to conduct a confidential and anonymous survey of employees' concerns about safety. Telos reported that "[w]e have never seen a site where the notion 'I could die today' was so real." Parus tried to make the case against further cuts, taking the drastic step of presenting a PowerPoint containing photographs of workers killed in plant accidents to Manzoni and Hoffman. Manzoni and Hoffman did not yield.

BP ultimately settled the private lawsuits brought by families of the employees who had died for a total of $2.1 billion. It settled Clean Air Act felony charges brought against the company by the Environmental Protection Agency (EPA). No individual was ever prosecuted criminally as a result of these events.

The Deepwater Horizon

> The immediate causes of the Macondo well blowout can be traced to a series of identifiable mistakes made by BP, Halliburton, and Transocean that reveal such systematic failures in risk management that they place in doubt the safety culture of the entire industry.
>
> National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling, *Deep Water, The Gulf Oil Disaster and the Future of Offshore Drilling*[4]

The Well from Hell

The gigantic derrick loomed 20 stories above the sea, the centerpiece of a $350 million, 30,000-ton drilling rig named the Deepwater Horizon. Stationed 49 miles offshore in the Gulf of Mexico and poised above a nine-square-mile underwater oil field quixotically named Macondo, the Deepwater Horizon was owned by Transocean, the largest rig provider in the world, and leased by BP, one of the biggest oil companies in the world, for the princely sum of $1 million per day.

From the beginning, the well field posed exceptionally difficult geological challenges. BP and Transocean employees on the front line of the project started referring to Macondo as the "nightmare well" or "the well from hell." Drilling began in 2009, but ended abruptly in November when the Marianas, another Transocean rig, managed to sink a hole 4,000 feet below the seabed but was so badly damaged by Hurricane Ida that it had to be hauled away for repairs. BP and Transocean were not ready to try again until more than a year later, in January 2010, when they positioned the Deepwater Horizon directly over the uncompleted well, with the goal of drilling a hole 2.5 miles beneath the surface, making it among the deepest in the Gulf or, for that matter, the world.

The schedule for completion of the project called for 51 days of drilling at a cost of $96.2 million. But the drilling lagged six weeks past that deadline, with cost overruns of $58 million. Finally, on the morning of April 20, 2010, the Transocean crew, in consultation with the onsite BP "company man" and a squadron of BP engineers based in Houston, Texas, prepared to complete the temporary abandonment of the well, which by then was 18,400 feet deep (5,000 feet from the surface of the Gulf and 13,000 feet below the ocean floor). The Deepwater Horizon would move on to a new drilling job, and BP would install a permanent production platform to extract the oil.

The Deepwater Horizon was a state-of-art "semi-submersible platform" with sleeping quarters for 126 crew and several guests. The living space sat atop a gigantic platform housing the derrick, staging areas for heavy drilling equipment and piping, huge pits for recirculated drilling mud, and a helicopter landing pad to accommodate frequent trips to and from shore. Giant pontoons positioned 130 feet beneath the surface kept the rig afloat, and sophisticated computers and heavy motors maintained the rig's vertical position above a riser pipe. The pipe itself was made of giant, three-story high segments that were screwed together and extended thousands of feet into the well.

The Blowout

At 9:45 p.m. on April 20, drilling mud erupted from the wellhead, pouring over the Deepwater Horizon's deck. The huge rig began to shake. The explosion that followed consumed much of the rig in flames as crew tried desperately – and far too late – to trigger the blowout preventer designed to shut the well opening in an emergency. By the time they tried to activate that last line of defense, the piping at the bottom of the well had bent, and the shearing rams could not seal it. Panicked by flames and smoke, with some seriously injured by flying debris, people jumped 125 feet into the water below while others struggled to lifeboats. When they reassembled on a supply boat mercifully located nearby, eleven men were missing and the gaping hole in the seabed was beginning to pour oil into the Gulf. That leak would last for 87 days, depositing 210 million barrels of crude oil into the Gulf. (By way of reference, the 1989 Exxon Valdez spill in Alaska's Prudhoe Bay spilled an estimated 30 million gallons, albeit much closer to shore.)

This catastrophe for workers and the environment should not have been a surprise to anyone familiar with deepwater oil production. By far the most serious hazard on any deepwater rig is a blowout of oil and gas deposits held under enormous pressure within rock formations located deep underground. Once drilling reaches any significant deposits, kicks – or explosive releases – can occur. To equalize the pressure between the drill pipe and those deposits, crews pour drilling mud –a thick, viscous sludge manufactured of oil, synthetic fluids, polymers, and chemicals that is roughly twice the weight of water – down the pipe. The mud serves the dual purpose of keeping the drill bit relatively cool. Drilling mud is constantly recirculated in a deepwater well. When it reaches the rig, equipment filters out chunks of rock and other debris displaced by the drilling and the mud is then pumped back into the pipe. The influx of mud must be carefully monitored because, if the load in the pipe becomes too heavy, the pipe can sway, running the risk of fracture.

The process of closing a deepwater well temporarily is significantly more hazardous than daily operations. It requires days of effort, as teams struggle to stabilize the casing that shore up the long column through which the drilling equipment has penetrated, slowly withdrawing that equipment while filling the mouth of the well with specially formulated cement, all in murky depths with unmanned equipment that is difficult to position and read. If a kick occurs and is large enough, it displaces the drilling mud and seawater inside the pipes, traveling at frightening speed to the surface, where it erupts within the rig, catching fire and exploding. To protect the rig and its crew from this dangerous condition, a gigantic piece of equipment known as a "blowout preventer" or BOP is positioned near the bottom of the well. In the Deepwater Horizon's case, the BOP weighed in at an impressive 300 tons (roughly 12 garbage trucks) and stood five stories high, with shearing rams that could close the pipe in the event of an emergency. In the aftermath of the disaster, much was made of the BOP's failure to close the well, and investigators found that this critical piece of equipment had not been maintained properly. But the key failure was that the crew did not activate the BOP in time and by the time they did try, the pipe was twisted and could not be cut. In any event, the BOP failure was just one of several very serious mistakes that caused the blowout.

Fatal Errors in a System Without Accountability

Aboard the Deepwater Horizon, the combined factors of the well's depth and fragility and the delays and cost overruns exhausted the onshore and onsite crews. All were feeling tremendous pressure to plug the well and move on. Compounding the technical difficulties of the process is the fact that employees working for several companies were integrally involved in the chaotic decision-making. No single person had full authority and no one was ultimately responsible for managing the process.

Plans for drilling the well were compiled with meticulous care, over many months, with schematics approved by federal regulators. But temporary closure was a surprisingly hurried and chaotic affair implemented over a single week. Corners were cut. Decisions were made in large groups, ostensibly by consensus. Self-justifying emails with large attachments were circulated to long lists of recipients; some never opened these documents. Lines of communication became twisted, then frayed, and finally shorted out.

Most accounts of detailed investigations conducted after the blowout focus on five decisions deemed to be the most important causes of the blowout. The risk they created was cumulative.

Among the first steps in accomplishing temporary abandonment of the well was to insert a new liner – or "production casing" – into the well. BP and Transocean had two options: setting a "long string" or using a "liner and tieback." Both had pros and cons, although the second option was the most commonly used, was more expensive, and, while it had the potential to cause more problems when the well converted to production, it was considered significantly less risky during temporary abandonment. BP chose the less expensive, more risky long string.

BP's plan to close the well called for the gradual removal of all drilling mud and its replacement with much lighter seawater. This process is precarious because the drill shaft may sway, causing drilling mud and cement to mix together and preventing cement from reaching the bottom of the well and setting properly. To prevent this development, deepwell developers use equipment known as "centralizers" to stabilize the shaft. When BP confirmed its choice of a long string, Halliburton engineers ran models, concluding that no fewer than 21 centralizers would be needed to ensure that uncontaminated cement reached the well bottom. After significant email traffic, BP engineers made the decision to go with six, primarily because it would have taken an additional ten hours to install the full 21.

In consultation with Halliburton, BP managers had decided to use "nitrogen foam cement" – a formula that was lightened by the addition of tiny bubbles of nitrogen gas. The advantage of this lighter cement was that it was less likely to fracture the fragile rock formations around the well, avoiding a surge in pressure, a potential kick, and possibly a blowout. On the other hand, testing showed that the lighter cement was significantly more prone to failure. BP engineers rationalized that if the initial effort to plug the well with the lighter cement did not work, the crew could launch a remedial "squeeze" job that involved making holes in the piping near the bottom of the well, and squeezing reinforcing cement through the holes. For the engineers, trying one approach first and then turning to the alternative made commercial sense: they would save millions if the first job worked. No one appears to have considered the possibility that given the unpleasant

alternative of spending more money, the crew would fall into the trap of "confirmation bias" – straining to ratify their initial decision regardless of evidence that it was wrong, and this outcome is exactly what happened.

BP managers then made another, inexplicable one mistake. They had hired a team employed by the consulting firm Schlumberger to perform testing called a "Cement Bond Log" that was designed to verify that the cement was in place and was holding. Schlumberger sent a team to the rig, and it was ready to conduct the test the day before the blowout. But BP managers decided to cancel the test and send the team home. This decision saved the cost of the test – about $128,000 and about 10 hours of time, making it among the most penny-wise and pound-foolish decision in modern corporate history.

BP's last-minute plan for completing temporary abandonment of the well was distributed to the Transocean crew at an 11:00 a.m. meeting on the fateful day in the form of a seven-step list labeled as an "Ops Note." This plan had undergone four iterations in the nine days leading up to its distribution. "There is no evidence that these changes went through any sort of formal risk assessment or management of change process," the Commission stated flatly. Steps one and four of the seven-step protocol called for the performance of a "positive-pressure test" and a "negative-pressure test" to confirm the well's "integrity," or, in other words, that the casing could withstand deepwell pressure and that the cement job was not leaking. The positive pressure test began at noon. The well passed this test.

The negative pressure test involves simulating the lower pressure in the well that would occur when the cement sets and the well is temporarily abandoned. The first step in the test is to bleed off any pressure that had built up in the well down to zero pounds per square inch (psi) in the drill pipe. If no liquids or gases flow up from inside the well and the pressure does not increase within the piping, the test would show that the well was sealed. The crew accomplished these conditions by putting a large quantity of so-called "spacer fluids" down the pipe. The fluids were supposed to separate oil-based drilling mud from seawater. Once this separation was accomplished and the heavy drilling mud was isolated from the seawater, they could reduce pressure in the pipe. But the crew did not use conventional spacer fluids that were specifically designed to accomplish this result. Instead, the engineers convinced themselves that they could use two batches of material that they had on hand to patch fractures in the rock formations leading to the well. They wanted to reuse these materials because the only alternative was to haul them back to shore and pay to have them disposed of as a hazardous waste.

To make a long story short, the negative pressure test on the drill pipe did not work. The test began at 5:00 p.m. The crew was unable to get the pressure below 266 psi and even then, it jumped to 1,262 psi after a short time period. The crew tried two more times to lower the pressure. Each time, the pressure initially fell to 0 psi but soon rose again. At this point, an ad hoc group of men present near the control room accepted a remarkable theory advanced by Jason Anderson, a senior toolpusher on the rig who had spent ten years on the Deepwater Horizon and had considerable influence with other members of the Transocean drilling crew. According to Anderson, the rise in pressure – essentially, the failure of the test – could be explained by a phenomenon he had heard about called the "bladder effect." He said that leaking around the rubber rings used to seal the gaps between segments of drill pipe allowed enough pressure to

infiltrate the drill pipe and cause a small kick. Because the source of the pressure was infiltration from the leaking rings, high readings did not mean that the well itself was leaking.

In the aftermath of the blowout, investigators were unable to find any engineering expert in deepwater drilling willing to acknowledge the validity of this theory, which appears in retrospect to be akin to an urban legend, albeit with catastrophic consequences. Jason Anderson was killed in the explosion, blunting somewhat the retrospective criticism of the theory. The two BP "company men" on the rig – Robert Kaluza and Donald Vidrine, who would later be indicted for 11 counts of manslaughter – initially expressed skepticism about the theory, but eventually backed down in the face of ridicule by the tool-pushers and their own confusion. Remarkably, neither man thought to consult with engineers in Houston.

Upon completion of the jerry-rigged negative pressure tests, the crew had one final opportunity to confirm that the well was ready to be closed: monitoring the outflow of drilling mud as it was pumped from the pipes and displaced with seawater. The amount of mud should be the same as the amount BP had sent into the well. If the total volume was less, the shortfall would constitute a serious warning that the well was leaking, the cement job had not worked, and a kick was possible. But, once again, a fatal shortcut was taken. Rather than pumping the mud into huge containers on the surface of the rig's deck where it could be measured, it was pumped overboard into supply vessels moored alongside the Deepwater Horizon. At some point, the pumping was redirected into the sea. Both practices were a serious departure from routine protocols.

Aftermath

On November 15, 2012, Attorney General Eric Holder announced a settlement of criminal charges against the company that collected an unprecedented total of $4.5 billion in fines and other penalties. This huge amount included $525 million to settle charges developed by the Securities and Exchange Commission (SEC) that BP had deliberately misled investors by claiming that the size of the spill was 5,000 barrels per day when the company had developed data indicating that the well was gushing far more than that amount. In February 2013, the DOJ settled a case against Transocean for Clean Water Act violations for $400 million in fines. Federal prosecutors collected $200,000 in criminal penalties from Halliburton for destroying evidence – namely, modeling conducted several weeks after the blowout that showed the safety implications of using 21 as opposed to 6 centralizers. Halliburton also agreed to donate $55 million to the National Fish and Wildlife Foundation. The Justice Department obtained indictments against BP mid-level managers Robert Kaluza and Donald Vidrine, the well supervisors or "company men" aboard the Deepwater Horizon, and their trial is expected to begin in the next few months.

Led by ExxonMobil, which has its own ragged history of environmental damage, the largest American oil companies have gone to considerable lengths to advance the dual theories that BP is a rogue company and that apart from the Macondo blowout, which was caused by BP's unique brand of corporate recklessness, deepwater drilling in the Gulf is absolutely safe. In testimony before Congress in June 2010, the chairmen of ExxonMobil, Chevron, Shell, and ConocoPhillips portrayed BP as an outlier in the industry and claimed that they do not operate as it does, especially with respect to cutting corners to save time and money. "We would not have drilled

the well the way they did," pronounced Rex Tillerson, chief executive of ExxonMobil. The Oil Spill Commission explicitly rejected this conclusion, highlighting the active participation of Transocean and Halliburton in the fiasco of decision making that preceded the blowout as the best evidence that inappropriate risk-taking is an industry-wide problem.

The backbone of the claim that BP was a rogue on a reckless mission is the company's admittedly terrible track record with respect to regulatory violations. BP certainly leads the industry with respect to Occupation Safety and Health Administration (OSHA) citations for violations of workplace safety requirements, primarily because of the unusually rigorous inspections to which it was subjected after the Texas City refinery explosion in 2005. But other companies have hosted comparably deadly – and avoidable – incidents. For example, in 2010, seven workers were killed at a Tesoro refinery in Washington state.[5] In 2012, a fire at a Chevron refinery located on the San Francisco Bay sent thousands of residents to local hospitals.[6] When the OSHA responded to these episodes by expanding and intensifying its inspections within the refinery sector, an effort that continued until the agency ran out of funding, it concluded that poor maintenance and ineffective safety systems are chronic throughout the industry. A 2010 study done by the private sector group RiskMetrics – which used as indicia fatalities, injuries, spills, and regulatory citations – found that although BP was in the bottom quartile of companies included in the survey, Shell and Chevron joined it there, while ExxonMobil landed in the second-lowest quartile.

Meanwhile, the push out to the edge of the envelope of what technology can manage safely once again picked up speed. One excellent example of the risks at stake in this development is a $3 billion rig called Perdido, a Spanish word that, depending on context, can mean lost, incorrigible, or in trouble. Other rigs share equally unfortunate names, such as Blind Faith, Mad Dog, and Atlantis. Perdido is operated by Royal Dutch Shell in water 9,600 feet deep at a mooring point 200 miles from shore. Supply boats must travel 20 hours to reach it. The Perdido is designed to produce up to 130,000 barrels of oil daily, relying on a complex web of wells that will extend 30 miles on the ocean floor. Instead of pumping oil to the platform and separating oil from gas and water there, as is done at the vast majority of comparable facilities, engineers designed new separation equipment on the sea floor near the wells, improving efficiency, but making equipment much harder to monitor and repair. Water at those depths wreaks havoc with equipment, especially when hurricanes, which have increased in intensity, sweep through the Gulf. How the Perdido would be evacuated in the event of a severe blowout is unclear.

The Upper Big Branch Mine

> It's like a jungle, where a jungle is the survival of the fittest; unions, communities, people – everyone is going to have to learn to accept that in the United States, you have a capitalist society, and that capitalism, from a business standpoint, is survival of the most productive.
>
> Don Blankenship, former chief executive officer of Massey Energy[7]

An 'Entirely Preventable' Disaster

On April 5, 2010, at approximately 3:02 p.m., just as two of three daily, eight hour shifts were changing places, a massive explosion shook Massey Energy's Upper Big Branch (UBB) mine in Montcoal, West Virginia. The explosion of combustible coal dust spread over two and a half miles in mine shafts 1,000 feet underground. It traveled at speeds up to 1,500 feet per second, packing an overwhelming force of up to 65 pounds per square inch. The explosion roared through underground tunnels, hit walls, reversed direction, and came back again. Twenty-nine miners died and one was seriously injured in the worst U.S. mine disaster in four decades.

Veteran rescue experts said they had never seen so much destruction over so great an area, with rail ties twisted like pipe cleaners, and equipment blown to bits. Toxic gas produced by the blast was pervasive, even affecting aboveground rescue teams attempting to bore vent holes into the mine. Recovery of the dead took days because travel to the blast site was dangerous and time-consuming, requiring a slow ride in low-slung "man trips" that traveled on rails from the mine entrance two miles away. The dead were scattered in small groups, thousands of feet from each other, felled either by the force and heat of the explosion or suffocated by carbon monoxide. One miner's remains were impaled on the ceiling.

UBB never reopened for mining.

In the aftermath, a series of investigations were launched that involved joint interviews with 269 witnesses and review of 88,000 pages of documentary evidence. The only participants omitted from the investigation were 18 senior Massey executives who invoked their Fifth Amendment right against self-incrimination. Technical experts walked through what was left of the mine, conducting extensive testing of burned materials throughout the blast area and examining cracks in the floor and walls to discover sources of explosive methane gas. Extensive reports were produced by (1) Mine Safety and Health Administration (MSHA) regulators; (2) an independent panel of experts appointed by then West Virginia Governor Joe Manchin (D-WV) (he is now a U.S. senator); (3) the National Institute for Occupational Safety and Health (NIOSH), which was asked to evaluate the MSHA's internal evaluation of the disaster; (4) the West Virginia Office of Miners' Health, Safety, and Training (MSHA's state counterpart); and (5) the United Mine Workers of America (UMW) (the union that represents miners across the country).

The five teams pronounced the tragedy (to use MSHA's words) "entirely preventable," and blamed chronic violations of safety rules as the primary causes of the explosion. They concluded

that if Massey had complied with the law, the tragedy could have been avoided or would have been far more limited in scope.

Three Life-Threatening Hazards

All of the reports focused on the three most important and life-threatening hazards that accompany the extraction of coal during the "longwall mining" that was practiced at UBB and many other high-production, modern mines. Mining companies install huge, long, and relatively narrow machines mounted on tracks along a mine wall, with powerful rotating blades on one side used to cut through coal. The UBB machine was capable of making 1,000 feet passes along the wall before it reversed and traveled back in the opposite direction. As the blades chewed through the coal, chunks fell onto conveyor belts and were carried out of the mine. A roof was installed over the track to protect miners and the machine from falling rock and other debris. Longwall machines produce only isolated sparking when they move through coal, but when they reach the sandstone that is intermixed with the coal, they can produce "hot streaks" or sustained sparking. To prevent hot streaks from igniting ever-present methane gas, the longwall machine has nozzles designed to spray a steady stream of water when the machinery is cutting a mine wall in order to douse any flames. But seven of the nozzles on UBB's longwall equipment were missing, and others were often blocked by grit contained in the river water used to fill water tanks on the machine.

The buildup of methane, which is a plentiful by-product of extraction, is a pervasive problem in deep mining because the gas is odorless, colorless, and poisonous in concentrated amounts. UBB was well known as a "gassy" mine that produced plentiful methane. Methane is the reason why miners in the nineteenth century brought cages of canaries into shafts. The canaries would drop dead when the lethal gas rose to dangerous levels, alerting the miners to abandon the area. Today, electronic monitors have taken the canaries' place, but they must be in operating condition and miners must pay careful attention – and must be allowed by management to pay careful attention – to the alarms they sound. Monitor maintenance was not a top priority at UBB. Moreover, concrete block barriers, removable curtains, and air lock doors scattered throughout the mine were designed to channel methane away from active mining areas, but the curtains and the doors were often taken down or left open to increase the pace of coal production.

Closely related to methane buildup is the urgent need to design and build effective ventilation systems that bring clean air from the surface into the mine. These channels are fed by gigantic fans drawing air from the surface. MSHA is so concerned about the correct operation of such systems that it requires mining companies to get its approval of the initial design and any subsequent modifications. UBB's ventilation system was inordinately complex because it had been built on the cheap. Instead of semi-permanent barriers that provide the best capacity to direct air but are more expensive, Massey had installed many air lock doors and curtains that required constant manipulation to maintain appropriate levels of clean air. Miners in a hurry frequently left the doors open or removed the curtains, interfering with their capacity to prevent the infiltration of methane and carbon monoxide (CO).

Compounding these problems, on the day of the explosion, mine tunnels were flooded with water because pumps designed to keep them clear were turned off the previous day, which was Easter

Sunday. When the pumps were turned back on, they malfunctioned. Maintenance crews spent much of the first day shift wading through neck-high water trying to fix them. The flooding further interfered with the flow of available air. Worse still, several witnesses said that UBB's fans seemed to be operating in reverse, sucking fresh air out of the mine rather than pushing it into areas where miners were working.

The final and most important hazard is highly combustible coal dust. MSHA has strict rules requiring mine operators to constantly suppress this dust by spreading inert gray "rock dust" over all active mining surfaces. Massey's rock dusting crew consisted of three men who were so overburdened with other work that they could only work part-time on this vital task, neglecting rock dusting for days at a time. The mine had two rock dusting machines, but one was inoperable and used only for spare parts.

The Blankenship Way

On the day that UBB exploded, the Federal Mine Safety and Health Review Commission (FMSHRC), the small federal agency that handles safety citations appealed by mine owners, had a backlog of 18,000 cases, involving $210 million in potential penalties. Massey Energy was among the most enthusiastic filers of appeals, challenging 34 percent of its citations in comparison to a national average of 27 percent. Citations involving Massey accounted for 11.2 percent of the FMSHRC total and represented $10 million in the penalties sought by MSHA enforcers. As these numbers indicate, Massey and UBB were becoming a significant drain on MSHA resources. In 2009, MSHA inspectors spent 1,854 hours at UBB, twice the time they spent in 2007. During the first three months of 2010, leading up to the April explosion, MSHA inspectors had already logged 803 hours at the mine. The rise in citations was accompanied by disturbing increases in injury rates: UBB's "Operator Nonfatal Days Lost Rate" increased by 100 percent in 2007–2009, up from 2.41 to 5.81 per 200,000 hours worked. The national average over the same period declined from 4.75 to 4.03.

To their credit, despite Blankenship's recalcitrance and the inability of Washington, D.C. reviewers to process appeals of citations in a timely manner, line inspectors stuck to their guns. The Federal Mine Safety and Health Act authorizes MSHA inspectors to issue "withdrawal orders" requiring the immediate evacuation of work areas if they discover violations serious enough to present a health or safety hazard. (The main health hazard in coal mining is black lung disease; safety hazards include fire, an explosion, or a roof collapse.) Mine operators get one warning and a chance to fix the problem, but if an inspector returns within 90 days to find the same hazard unaddressed, he may issue a withdrawal order. Such orders are effective immediately with limited opportunity to appeal. They are taken quite seriously by the industry because they halt production. Miners may not return to the area of the mine targeted by the order until the problem is fixed.

In 2009 and the first three months of 2010, UBB was subject to 61 withdrawal orders, a large and in retrospect, foreboding amount. The most common violations cited by the MSHA involved UBB's most serious and chronic problems: bad ventilation (the subject of 23 percent of citations nationwide) and inadequate coal dusting (24 percent).

On the fateful day of the explosion, the day shift crew encountered repeated mechanical problems with longwall equipment. It ran along its 1000-foot track between 7:30 and 11:00 a.m., but then was shut down between 11:00 a.m. and 1:30 p.m. because a piece had fallen out of the equipment. Ventilation was once again a problem, and methane gas was seeping from the mine wall into the area where the men were working. When they started running the machinery again between 2:30 and 3:00 p.m., one of the bits struck sandstone, producing a spark that ignited 3,000 cubic feet of methane mixed with air – the equivalent of a 19- by 20-foot room with an eight-foot ceiling. The resulting fireball might have killed or severely injured miners in the immediate vicinity of the longwall but would never have caused a massive explosion were it not for the large quantities of coal dust floating in the air. All of the investigative reports concluded that central cause of the accident was inadequate rock dusting. As United Mine Workers (UMW) investigators explained:

> The only logical explanation for an explosion to travel seven miles underground is that it had to have been propagated by a continuing supply of highly explosive fuel. The only available fuel supported by the evidence that is sufficient to propagate an explosion of this magnitude is float coal dust.

Aftermath

U.S. Attorney for West Virginia Booth Goodwin indicted Don Blankenship on multiple counts of ignoring mine safety requirements, defrauding the U.S. government, and securities fraud. At this moment, his case is in front of a jury. If convicted he could spend the rest of his life in jail. Blankenship is one of the most notorious white collar criminals ever brought before a federal court, but none of the egregious and unsafe practices described above would have been possible without the cooperation of a dozen or more lieutenants who succumbed to his threats that they would be fired if they did not take shortcuts in order to "run coal."[8]

The Peanut Corporation of America

> If someone is convicted of a felony in the criminal justice system, they go to prison and are not allowed to vote. But, if you poison Americans via their food supply what are the consequences? You pay a fine and keep producing? Is this right? Is this what we as Americans want?
>
> Peter Hurley, police officer, Portland, Oregon and father of surviving salmonella-poisoned child[9]

Team Diarrhea's Discovery

In the fall of 2008, Minnesota public health officials were alarmed by an unusually high number of illnesses and deaths caused by salmonella poisoning. This outbreak of foodborne disease, one of the largest in history, ultimately resulted in the deaths of nine people and sickened 714. About one-quarter of those made ill were hospitalized and half of the ill were young children. Medical experts who have studied the incident say that even these high numbers likely underestimate the outbreak's impact because salmonellosis remains a significantly underreported disease. They say that the number of illnesses and deaths could be as much as 16 times more than reported.

Graduate students employed by the Minnesota health department and jokingly referred to as "Team Diarrhea" deployed the tedious and time-consuming "trace-back process," which involves interviewing victims and their families in detail about what they ate in order to discover common foods. Once they established links between what sick people ate, experts at the Centers for Disease Control and Prevention (CDC) undertook sophisticated testing of the suspect food, reporting their results on PulseNet, the national molecular subtyping network for foodborne contaminants that allows scientists to develop genetic profiles of such bacteria. Federal and state government officials concluded that the victims had all consumed peanut products supplied to schools, nursing homes, and other institutions by the Peanut Corporation of America (PCA) from its facilities in Blakely, Georgia, and Plainview, Texas. The company made peanut paste used in a wide variety of products, from cereal to desserts to pet food. Large food producers such as Kellogg's and Nestlé had been PCA customers, as was the federal government, which bought peanut products for low-income schools, the military, and victims qualifying for disaster relief. Salmonella is a bacteria found in the intestinal tract of animals.

Salmonella is introduced into the food supply through the spreading of animal waste. Once peanut products are contaminated, the bacteria can survive during their entire shelf life of peanut products – from 18 to 24 months. Illnesses caused by salmonella exposure include symptoms such as nausea, vomiting, and diarrhea. Healthy adults generally recover within a matter of days. Children, the elderly, and people with compromised immune systems are far more vulnerable to serious debilitation. Salmonella poisoning can spread from the intestines into the bloodstream and cause death in acute cases.

Although the Food and Drug Administration (FDA) lacked legal authority to demand that products containing PCA peanuts be pulled off the shelf – a stunning gap in the law that has since been fixed – the agency persuaded PCA to recall voluntarily all the shipments it produced

in 2007 and 2008. Publicity inspired its customers to broaden the scope of the alert. Before the incident was over, the FDA website listed some 3,900 products as potentially affected. The site received 28 million hits as consumers consulted it to determine whether their kitchen cabinets held potentially dangerous food.

Mice, Roaches, Bird Feathers, and a Leaking Roof

In the aftermath of the outbreak, federal investigators inspected PCA's Georgia and Texas plants rigorously. They discovered that in well-run facilities, salmonella is eliminated by roasting peanuts at temperatures of at least 350°F (180°C). But the roaster at the Georgia plant was not heating correctly for critical periods when raw peanuts were processed into peanut butter and peanut paste. The roaster was cleaned once a month rather than once weekly, which was the industry standard. In addition, peanuts roasted to eliminate salmonella can be re-infected if the finished product is not stored in sanitary conditions. At both the Georgia and Texas plants, storage areas were used for both finished products and potentially contaminated raw peanuts.

Federal inspectors further discovered that the Georgia plant's roof was leaking and mold was growing on its ceilings and walls. The plant was infested by rodents, with dead mice and "REPs" too numerous to count. (The acronym, a particularly pungent example of bureaucratic euphemism, stands for "rodent excretion pellets".) Receptacles used to process nuts were filthy. The air filtration system was caked with feathers, lint, and dust. Employees wore the same clothing to work as they used in the supposedly sanitary peanut processing area. Hand-washing facilities required employees to touch a filthy pedal to turn the water on and off, negating the sanitary advantages of the washing. Interviews with former employees filled out the picture.

Blakely employee David James told the Chicago Tribune that he opened a huge peanut "tote"– the industry name for a gigantic plastic bag used to store up to one ton of nuts – only to find baby mice living in it. "It was filthy and nasty all around the place," he said.[10] Terry Jones, a janitor, said that peanut oil was left to soak into the floor of the plant and that the roof constantly leaked into the plant. James Griffin, a cook, said he never ate the peanut butter, despite the availability of free samples, and would not let his children eat it.

Post-outbreak investigations also revealed that in April 2008, Canadian officials had rejected a "filthy and putrid" shipment of chopped peanuts from PCA because it contained metal shavings. The shipment was returned to Blakely and PCA workers made abortive efforts to "decontaminate" it so it could be resold. Federal inspectors visited the plant to ensure the shipment was destroyed, but for reasons that remain unexplained, did not notice the conditions that caused the Canadian problem and the subsequent salmonella outbreak.

As for the PCA facility in Plainview, Texas, investigators discovered that it had operated for four years without a license from the state. Of course, because officials did not know the plant existed, no inspections occurred before the outbreak. State inspectors added Plainview products to the recall list when they discovered that the plant's air handling system was pulling debris from a crawl space strewn with dead rodents, rodent excrement, and feathers into the areas where peanuts were processed.

PCA's malfeasance had a second twist. Managers routinely shipped products accompanied by paperwork that was deliberately falsified. For example, PCA products tested positive for salmonella 12 times in 2007 and 2008, but the company sold these lots to customers anyway after a retest produced negative results. "'The practice of initially obtaining a positive sample and subsequently of getting a negative results and not having cleaned up the plant is illegal," Michael Rogers, FDA director of the division of field investigation told the *New York Times*.[11] The defendants also falsified the Certificates of Analysis (COAs) sent to its customers to show that the product had been tested and that coliform and other bacteria were not detected. Most coliforms are not harmful in and of themselves but because they derive from fecal matter, they indicate that the product was not produced in sanitary conditions and that more dangerous organisms may be present, including bacteria, viruses, protozoa, and multicellular parasites. Plant managers went so far as to use test results from previously shipped batches to accompany batches that had not been tested.

Aftermath

On February 21, 2013, the U.S. Attorney for the Middle District of Georgia indicted Stewart Parnell, owner and president of PCA; Michael Parnell, his brother and a food broker who worked on behalf of PCA; Samuel Lightsey, operations manager of PCA's Blakely, Georgia, plant; and Mary Wilkerson, receptionist, office manager, and quality assurance manager at Blakely. Stewart Parnell was sentenced to 28 years in prison on September 22, 2015, the most severe sentence ever handed down for crimes that caused consumer deaths and injuries.

The New England Compounding Center

> The protections for your cat or dog are stronger than for your wife and children.
>
> Larry D. Sasich, research pharmacist[12]

Thousands of Vials Sold in 20 States

In the early fall of 2012, people across the country contracted virulent fungal meningitis infections after receiving spinal injections of methylprednisolone, a steroid drug used to relieve back and shoulder pain. Fungal meningitis causes inflammation in the brain or central nervous system; the disease develops one to four weeks after exposure. Difficult to treat, the disease can cause fatal strokes in some patients. Like a slow-moving plague, the illnesses and deaths mounted. By November 2013, 751 living in 20 states were ill and 64 had died.

Suspicious doctors and hospital officials eventually discovered that the injections had one characteristic in common: All had originated at the New England Compounding Center (NECC) in Framingham, Massachusetts, which had manufactured 17,676 vials of methylprednisolone that were administered to over 14,000 patients. As federal and state inspectors and the media converged on Framingham, NECC and its sister company, Ameridose, surrendered their pharmacy licenses and soon shut down. Under heavy government pressure, company executives launched recalls of suspected shipments. In December 2012, NECC filed for Chapter 11 bankruptcy protection.

Hospitals and doctors have mixed special drugs – or "compounded" – since the nineteenth century. Historically, drugs were compounded for three reasons: (1) some patients are allergic to components of mass-produced products and need special mixtures that do not include these ingredients; (2) children and the elderly may need doses of medicine not found in standardized products; and (3) when a person is taking a number of medications, mixing them into one dose may help the patient comply with the regimen ordered by her doctor. But in recent years, compounding became far more lucrative and pharmacists began to manufacture and market popular pain medications and other injections on a far larger scale.

The structure of the compounding industry also began to change dramatically. Two decades ago, an estimated 8,200 hospitals made the compounded drugs they needed for their patients in-house. But in the early 1990s, hospital administrators began to see the advantages of outsourcing this task. An enterprising pharmacist named Jim Sweeney set up a double-wide trailer in a California hospital's parking lot, and independent compounding was off to the races, growing from a handful of local firms to an estimated 3,000 outlets that make sterile preparations like the steroid drug that caused the NECC outbreak. According to the International Academy of Compounding Pharmacists (IACP), the industry's largest and most influential trade association, compounders sell somewhere between one and three percent of the $300 billion in annual prescription drug sales, providing 40 percent of all intravenous medications used in hospitals.

The business profiles of independent compounders range from small back rooms at local pharmacies that limit their business to the production of medicine for individual patients to far

more ambitious operations like NECC, which ship large batches of drugs to doctors and clinics across the country. Hospitals, clinics, and doctors' offices came to NECC and its counterparts because their prices were cheaper and because drug shortages have made some medications difficult to obtain. Reporting on the economic dynamics of the industry, the *Boston Globe* quoted an industry spokesman whipping up the troops at a 2002 trade show in Atlanta: "'Anybody know what the average margin on a compounded product is?' businessman Mickey Letson, then president of a major compounding supply company, asked [the] group. . . . 'Seventy-five percent minimum gross profits. Depending on what field you're in it can run into the thousands of percent.'"[13]

A License to Print Money

NECC was among the most aggressive of this new breed. The company had easily obtained licenses to sell drugs in as many as 44 states and an expanded sales team solicited orders from hospitals across the country. By 2013, the company had 49 employees. A former manager who spoke on the condition of anonymity told the *New York Times*: "It was a license to print money. I've never seen a business grow so fast."[14]

Another former employee, a quality control technician who also spoke anonymously to *New York Times* reporters, explained that he once tried to stop the production line because labels were missing from several vials of medicine. He was overruled by senior management: "The emphasis was always on speed, not on doing the job right. One of their favorite phrases was 'This line is worth more than all your lives combined, so don't stop it.'"

All this haste had a devastating effect on safety and quality control. The company maintained two "clean rooms" for the assembly of sterile drug products. Heedlessly cutting corners in defiance of well-known, industry-wide best practices, the air conditioning in those rooms was shut down between 8:00 p.m. and 5:30 a.m., exacerbating fungal and bacterial growth. Eric Kastango, a consultant who works with compounding pharmacies on quality control, told the *Washington Post*: "This reinforces the fact that this facility was just horrific. The amount of microorganisms in the clean room was out of control." He added that because of improper temperature control, the clean room became a "giant incubator for things to thrive. You never shut down the air conditioning in the clean room."[15]

During the first nine months of 2012, routine monitoring by NECC employees of the clean room sterility uncovered mold or bacterial contamination at more than 80 locations. Managers kept the facility operating without taking time for a thorough cleanup. When the FDA and state inspectors visited the Framingham, Massachusetts, facility following the 2012 outbreak, they discovered rusting equipment caked with green and yellow residue. One-fourth of supposedly sterile steroid vials contained visible "greenish-black foreign matter."[16] Fifty vials were revealed to contain fungus when they were sent for microscopic examination. A leaky boiler near the clean rooms spilled dirty water on the floor. The building that housed the pharmacy was next door to a recycling center operated by one of NECC's owners. It shredded household garbage, filling the air with small particles of debris.

Aftermath

Following the NECC salmonella outbreak, the FDA made the wise decision to undertake a "risk-based" audit of compounders. Targets were selected on the basis of warning signs, including serious adverse event reports, historical inspection data, and complaints about product quality. Twenty-eight facilities that met two of these three criteria, or that were associated with a reported death, were placed on the inspection list. Three more were added on the basis of information discovered during the initial round of visits, for a total of 31 in 18 states. The agency used specially trained and experienced federal inspectors, who teamed with their state counterparts in 90 percent of cases. The inspections were quite thorough, including visual observation of the production process; interviews with technicians and management; and review of documents on the firm's operations, standard operating procedures, and products, especially with regard to sterilization and drug stability. Investigators collected samples where appropriate, and also researched episodes where failures had occurred with respect to potency, sterility, and endotoxins.

The agency had completed 29 of 31 inspections by April 2013, and it issued a Form 483 (bad conduct report) to 28 of that number. (The lone exception was not manufacturing sterile drugs.) The Form 483 reports are depressing reading. Frequently mentioned are the same universe of problems turned up at NECC: multiple violations of best practices to preserve sterilization, from gloving to gowns to effective sealing of clean rooms; failure to calibrate equipment; lack of written procedures; inadequate testing of finished products to detect dangerous contamination; poorly trained personnel; and filthy equipment. How the FDA will pursue these multiple violations is not yet clear.

Given the growing evidence that the compounding industry harbors a significant number of firms with practices similar to NECC's and daunting challenges that the FDA and the states still confront in preventing further outbreaks, you might expect that Congress would take the opportunity to pass a new law straightening out confusion over the FDA's legal authority and giving the agency the tools it needs to crack down on the worst actors within this little industry. And, if history was any guide, you would be right. Congress typically passes new, more stringent laws whenever a public health or environmental crisis has emerged until recently. Lack of action is bad, but it pales in comparison what happened in the wake of the NECC crisis.

Congress passed a shockingly weak new law, hailed as a wonderful example of bipartisanship in an era of anything but. The new law does not require compounders to register with the FDA unless they elect voluntarily to do so, and it does not increase either the civil or the criminal penalties that the agency can impose in the event that a compounder ships tainted drugs to customers. Instead, the law depends on compounders that make sterile drugs without individual prescriptions to volunteer to become official "outsourcers" of compounded drugs. A voluntary choice to participate in the system triggers an obligation to pay user fees to support FDA oversight and subjects the facility to periodic FDA inspections. Sponsors of the legislation rationalize this system on the basis that "market forces" would drive most compounders to register, as hospitals and other customers would refuse to do business with unregulated firms. The new law does not strengthen the FDA's authority to enter and demand written records from suspect compounders who do not volunteer for such treatment.

On December 17, 2014, the Department of Justice unsealed a 131-count indictment against 14 people who worked at NECC. Barry Cadden, owner and head pharmacist, and supervisory pharmacist Glenn Chin were charged with 25 acts of racketeering, conspiracy and second degree murder in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee, and Virginia. They are expected to go to trial within the next several months.

Volkswagen

Eleven Million Cars, 60 Premature Deaths, 35 Percent of Share Value, and Counting

Volkswagen's (VW) marketing strategy in the United States has been to promote the image that it is an iconoclast. In the land of lumbering SUVs and stodgy mini-vans, it sold frisky, little, fuel-efficient, diesel cars named the Rabbit and the Beetle for people who are as proud of their social consciousness as they are thrifty. The image grew via a series of tongue-in-check, deliberately humorous advertisements. For example, a television advertisement shown during the 2014 Super Bowl shows a jovial dad and his sulky teenage daughter riding along in their VW just as the odometer changes to 100,000. The father tells the child that this milestone is very significant and asks what she would say if he told her that every time a VW car hits it, a German engineer "gets his wings."[17] A happy tune starts to play and a series of men in white coats wearing safety glasses and hard hats suddenly sprout very large sets of white, feathered angel's wings with appropriate parachute-opening sound effects.

Had the brand been less self-consciously righteous, the EPA's public announcement at the end of September 2015 that VW had installed software that turned off "air emission control devices" (AECD) in 500,000 cars driven in America might have inspired somewhat less outrage. Yet given such strong branding, people felt betrayed as well as cheated. In Europe, matters went from bad to worse when the company acknowledged that 10.5 million cars were affected worldwide, most of them on that continent. Six weeks later, another large shoe dropped when the company admitted to underestimating emissions of carbon dioxide (CO2), a cause of climate change, and overstating fuel economy for 800,000 European vehicles.

The U.S. DOJ immediately launched a criminal investigation, which is ongoing. Authorities in thirty states opened their own inquiries and the plaintiffs' bar filed lawsuits for consumer damages across the country. German authorities began their own inquiry, while in Paris, prosecutors raided the company's offices and seized computers. VW hired an American law firm, Jones Day, to carry out an internal investigation. Its chief executive officer, Martin Mitterkorn, resigned a few days after the first scandal broke, and was replaced by Matthias Muller, who came from Porsche, another VW brand. The company's share value fell by 35 percent within a few days of the announcement. The diesel scandal may cost the company $7.5 billion and the CO2 and fuel efficiency scandal another $2.2 billion.

On November 9, 2015, the international rating service Fitch-Ratings-London (Fitch) downgraded Volkswagen Long-term Issuer Default Rating (IDR) to BBB+ from A.[18] "The downgrade reflects the corporate governance, management and internal control issues highlighted by the ongoing emissions test crisis related to up to eleven million diesel-powered vehicles," Fitch declared in its press release." It added that the company's corporate governance was "weaker than that of its main peers" because it had a "blocking minority" of only 20 percent [on it supervisor board] with respect to "voting resolutions," as well as "potential conflicts of interest on the part of some board members, and lack of independence and diversity at the supervisory board level."[19] Fitch said that VW had been slow to make changes regarding its two boards: one labeled as "management" and a second, with superior status, labeled "supervisory."[20] Although it

commended VW's voluntary disclosure that it had underestimated CO2 emissions, it said that this problem suggested that further bad news was likely to emerge, compromising "reputational damage" to the company that could undermine its funding ability."[21] The overall outlook for potential investors was "negative."[22]

At this early stage, details about which VW executives knew what when are not yet clear, although the company appeared to be working hard to throw various senior engineers under the proverbial bus to deflect closer scrutiny of its marketing, financial, and sales executives. Without a doubt, skilled software engineers were summoned to the rescue when someone senior at the company discovered in 2008 that the diesel models the company was counting on to take the American market by storm had AECDs that would not allow the cars to pass U.S. tests.

The "cheat device" the engineers designed for diesel cars accomplished the feat of informing onboard emissions control technology when the cars were subjected to an evaluation of its effectiveness at the independent testing facilities that periodically certify compliance. The rest of the time or, in other words, during every hour of their routine operation, the software turned the AECDs off. As it turns out, a vehicle's onboard computer operates in two modes—"on road" and "dyno"—with the second triggered only when the emissions are being tested. The chief reason why the defeat device was necessary on VW cars was that the company wanted to keep them light and small, and rejected more sophisticated emissions control systems used in heavier vehicles.

The existence of the cheat device was discovered almost by accident, when researchers at West Virginia University were testing fuel efficiency as cars were driven on road. The study was commissioned by a tiny environmental group trying to document that European air quality standards were more lax than those in the United States.[23] Two VW cars happened to end up in the initial mix of models subject to the first tests and the researchers were startled to discover that the cars gave off pollution significantly in excess of the stationary testing standard. The researchers took their findings to the EPA and the California Air Resources Board (CARB). Pinning down the exact nature and location of the cheat devices took considerably more time, and eventually VW was informed of the problem. It stonewalled the two regulatory agencies that spearheaded the investigation: the EPA, of course, and CARB. Finally, irritated by the company's arrogant attitude, the EPA announced its probe and the news traveled rapidly around the world.

In a sense, the fact that regulators got a tip on the problem from independent researchers was a lucky break that does not reflect well on their ability to prevent such violations. The discovery would be more reassuring had the regulators discovered the problem on their own. After all, the cheat device was in effect for seven years before the company admitted it existed, spewing pollution anywhere from 10 to 40 times national standards.

Although the media has focused disproportionately on the economic implications of VW's malfeasance, the results of the excess pollution sickened people and even triggered premature deaths. The pollutant at stake in the controversy was nitrous oxide (NOx), a precursor gas that combines with volatile organic compounds to produce ozone or, as it is more commonly known, smog.[24] Excess ozone is primarily a problem in the nation's major metropolitan areas. It is such a

serious problem that the EPA recently lowered the levels allowed in the ambient air significantly.[25]

The adverse health effects caused by excessive smog are devastating, especially to the very young, the elderly, or anyone else with compromised respiratory systems. A study conducted in 2013 by the Massachusetts Institute of Technology's (MIT) Laboratory for Aviation and the Environment found that 200,000 early deaths are caused by ground-level pollution, with emissions from road transportation the most significant cause.[26] The study further found that vehicle exhaust was a factor in 53,000 deaths. In October 2015, a study by scientists at MIT and Harvard University concluded that VW's cheat device, which resulted in pollution 10-40 times higher than applicable EPA standards, could result in as many as 59 deaths in the United States and impose "social costs" (*e.g.*, illness, days off work and school) of up to $450 million.[27]

As mentioned earlier, when the defeat device scandal emerged, VW's top executives took quick defensive action: They blamed the company's engineers. Michael Horn, head of the VW Group of America, told Congress that "a couple of software engineers" had invented the cheat device.[28] "To my understanding this was not a corporate decision," he added. "This was something individuals did."[29] Until the investigations are finished, this version of reality is difficult to dispute, although it is as self-serving as it seems impossible. At a company the size of VW, with the usual second-guessing at the mid-management level, could two isolated technocrats decide to take such a huge risk—engineering a piece of software that deliberately violates U.S. and European law?

The suspicion that the conspiracy extended further is confirmed by an excellent piece of reporting in the *Wall Street Journal*. VW's determination to push "clean-diesel" began a decade ago, under then-CEO Bernd Pischetsrieder, who lured executive Wolfgang Bernhard from rival company Daimler AG and made him the head of the VW brand.[30] Bernhard was also in charge of designing a new diesel engine, dubbed EA-189. He decided to license a superior emissions control system from his old company. Called "BlueTec" the system used urea to scrub emissions and was relatively large and heavy compared to VW's homegrown system. Its further disadvantage was that the consumer had to refill the urea tank periodically. As the engine design progressed, a corporate putsch resulted in the expulsion of Pischetsrieder, and Bernhard left soon after. The BlueTec license was cancelled, and VW reverted to its own, less effective system. Several people were involved in that decision, and it is difficult to imagine that when the VW pollution control equipment failed to satisfy the U.S. standard for NOx, its replacement by computer software was undertaken by a couple of engineers in a stealth mission.

In the end, VW could be charged with any of a number of crimes, including wire fraud (for selling cars that did not remotely justify the claims in its many advertisements) and making false statements to the government officials. Ironically, the one criminal charge the company and its executive are likely to escape is violating the Clean Air Act's requirement that all cars used in the United States have operational and effective air emissions control devices (AECD) approved by the government.[31] Former Representative John Dingell (D-MI), the longest-serving member of the House of Representatives and a staunch ally of the auto industry, made sure automakers were exempt, arguing, disingenuously, that civil penalties are "easier, speedier, quicker."[32] Fortunately, Senator Richard Blumenthal (D-CT), who is still in Congress and is a former

attorney general of the state of Connecticut with an excellent record of prosecuting cases to protect consumers and the environment, has stated that "the loophole should be closed."[33]

Endnotes

[1] THE HERITAGE FOUNDATION, USA VS YOU: THE FLOOD OF CRIMINAL LAWS THREATENING YOUR LIBERTY (2013), *available at* http://thf_media.s3.amazonaws.com/2013/pdf/USAvsYOU.pdf.
[2] This catastrophe occurred during the administration of President George W. Bush and individual executives were never prosecuted criminally despite clear evidence of criminal acts. Had they been, the BP Deepwater Horizon incident might never have happened.
[3] ABRAHM LUSTGARTEN, RUN TO FAILURE: BP AND THE MAKING OF THE DEEPWATER HORIZON DISASTER 133 (2012). Sawyer worked as a consultant to BP.
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About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information.

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Acknowledgements

CPR is grateful to the Bauman Foundation, the Deer Creek Foundation, and the Public Welfare Foundation for their generous support of CPR's work in general. This Issue Alert is by ***Rena Steinzor***, Professor of Law at the University of Maryland Francis King Carey School of Law and the immediate past president of CPR.