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## PHARMA'S FAILED PROMISE

**Exposing the Industry's Environmental Degradation in Puerto Rico** 



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#### CONTENTS

- 4 Executive Summary
- 5 Introduction: Environmental Racism in Puerto Rico
- 6 The Pharma Sector Has Created Toxic Waste Sites Impacting Dozens of Communities in Puerto Rico
- 11 | The Pharmaceutical Sector is Depleting and Polluting Puerto Rico's Drinking Water and Critical Groundwater Supplies
- 15 Community Exposure and Adverse Health Outcomes: Living Next to Toxic Waste
- 21 | Pharma's Decades of Ocean Dumping
- 23 | Pharma is Depleting Puerto Rico's Scarce Resources
- 28 | Policy Recommendations
- 29 | Press + General Contacts
- 30 Acknowledgements
- 31 | Methodology
- 32 Endnotes

## EXECUTIVE SUMMARY

**US PHARMACEUTICAL CORPORATIONS** are causing massive environmental damage in Puerto Rico. Not only are pharma giants extracting enormous tax breaks and profits from the archipelago, they are fueling environmental racism that harms millions of Puerto Ricans. Johnson & Johnson, Abbott, Merck, Pfizer, and others have created 15 toxic waste sites the Environmental Protection Agency (EPA) designated as "Superfunds." As the report highlights, pharmaceutical companies operating in Puerto Rico violate the Clean Air Act, deplete and pollute critical groundwater supplies that Puerto Ricans drink from, and flout critical environmental regulations. In the past three years alone, EPA data reveals that among the pharmaceutical facilities the agency monitors, one in three were cited for violating vital environmental protections. Amgen, Bristol Myers Squibb and more than a dozen other plants operating in Puerto Rico also faced EPA enforcement actions for serious environmental impacts.

Puerto Rican communities suffer enormous chronic health issues as a result, including high rates of cancer, asthma, and other respiratory illnesses. They contend with unsafe drinking water and toxic chemical exposures. Puerto Rico's government and US federal agencies are failing to hold pharma polluters accountable. Environmental racism often persists in Puerto Rico in the name of profits. Lax regulations, inadequate environmental cleanups, and government complicity with the pharmaceutical sector contribute to this ongoing problem. While pharma touts its commitment to human rights, carbon neutrality and renewable power grids, in reality, "corporate greenwashing" hides the full extent of the environmental devastation they cause in local communities. The report's findings highlight the urgent need for policymakers to investigate the pharmaceutical sector's environmental degradation in Puerto Rico while holding bad actors accountable through strengthened regulations and oversight measures.

## INTRODUCTION: ENVIRONMENTAL RACISM IN PUERTO RICO

#### PUERTO RICAN COMMUNITIES HAVE SUFFERED ENVIRONMENTAL RACISM FOR DECADES

The pharmaceutical industry extracts enormous profits from Puerto Rico while causing enormous environmental damage. Billion-dollar companies such as AbbVie, Merck, and Pfizer plunder scarce resources from Puerto Rico while harming the health of workers and communities on a massive scale. Since the late 1970s, scientists and advocates have uplifted the way the pharmaceutical industry has caused harmful environmental damage. They have pointed towards poorly enforced health and environmental laws as partly responsible for contributing to what Puerto Rican scholar and activist Dr. Neftalí García termed "environmental colonialism" in 1979. This pattern of colonial exploitation is responsible for Puerto Rico's environmental ills—as policymakers and companies have chosen to prioritize profits over breathing.<sup>1</sup>

Decades later, Hurricane Maria stripped bare how toxic industrial waste continues to blight Puerto Rico's landscape.<sup>2</sup> While promising economic gain, multinational pharmaceutical companies have contributed to a toxic stew of waste for Puerto Rican communities.<sup>3</sup> Communities like Arecibo suffer from piles of coal ash, toxic sludge, air pollutants, and pesticide chemicals, with inadequate regulatory activity from the Environmental Protection Agency.<sup>4</sup>

In comparison to some other more infamous examples of environmental damage, such as the five-story pile of coal ash in Guayama from the Applied Energy Systems coal plant,<sup>5</sup> or the US military experiments on Vieques,<sup>6</sup> the pharmaceutical industry's effects on the environment have generally been overlooked and understudied in the United States, making it easier for these corporations to evade accountability.

## THE PHARMA SECTOR HAS CREATED TOXIC WASTE SITES IMPACTING DOZENS OF COMMUNITIES IN PUERTO RICO

Superfunds are contaminated sites filled with hazardous chemical waste that industries have improperly handled. Companies have often left such waste out in the open to the harm of local communities.<sup>7</sup>

Congress established the Superfund Program in 1980 for the EPA to track, manage, and clean up the worst of these hazardous waste sites.<sup>8</sup> Of these, the National Priorities List (NPL) names the "most serious sites identified for long-term clean up."<sup>9</sup> The EPA uses a scoring system that determines what sites belong on the NPL based on "likelihood that a site has released or has the potential to release hazardous substances into the environment; characteristics of the waste (e.g. toxicity and waste quantity); and people or sensitive environments (targets) affected by the release."<sup>10</sup>

#### Puerto Rico contains over 500 Superfund sites

**total.**<sup>11</sup> As of July 2022, over half are still listed as "active," meaning these sites still pose danger to people living near them, and 18 are on the National Priorities List for the high potential risk that hazardous substances will hurt the environment or surrounding communities.<sup>12</sup> By comparison, Montana also has 18 toxic sites on the National Priorities List despite having a population one-third the size of Puerto Rico.<sup>13</sup>

#### The EPA has directly attributed 15 Superfund Sites to pharmaceutical manufacturing in Puerto Rico.<sup>14</sup>

Pharmaceutical companies have also contributed to additional Superfund sites by dumping toxic waste into landfills.<sup>15</sup> In addition, the EPA attributes four Superfund sites to the related medical device manufacturing sector on the archipelago.<sup>16</sup>

## EPA DESIGNATED "SUPERFUND SITES" ATTRIBUTED TO PHARMA AND MEDICAL DEVICE CORPORATIONS



## Pharmaceutical companies are responsible for some of Puerto Rico's most polluted sites.<sup>17</sup>

- In Barceloneta, pharmaceutical companies AbbVie, Merck, Pfizer, and Upjohn polluted the surrounding communities, prompting the EPA to designate four Superfund sites since the 1990s.<sup>18</sup> The EPA is still overseeing remediation and clean up of hazards at the UpJohn facility, which is currently on the National Priorities List for its extremely high concentration of toxic waste. One of UpJohn's underground storage tanks leaked into the groundwater, contaminating it with carbon tetrachloride (a highly toxic liquid used for insecticides, cleaning fluids, and refrigerants). While additional water sources were provided to the local community, and while UpJohn no longer manufactures at that site, the ongoing contamination resulted in the loss of an important groundwater supply.<sup>19</sup>
- In Arecibo, Pfizer leaked hazardous liquid materials through their poor waste management practices, contaminating nearby soil and groundwater. The chemicals consisted of chloroform, carbon tetrachloride, and acetonitrile. All three chemicals pose danger to the environment, but acetonitrile in particular is an extremely toxic liquid that dissolves easily in water.<sup>20</sup> The site used to be an UpJohn manufacturing site; Merck Sharp & Dohme Corp was located about a mile away.<sup>21</sup>
- In Guayama, TAPI contaminated the groundwater with benzene, chlorobenzene, ethylbenzene, methylene chloride, naphthalene, antimony, arsenic, lead, thallium, and vanadium.<sup>22</sup>

The EPA's Enforcement and Compliance History Online (ECHO) database tracks data on over 50 currently-operating pharmaceutical and medical device manufacturing facilities in Puerto Rico. Analysis of EPA data reveals that 18 of these facilities—or one in three were cited for environmental violations on the archipelago in the last three years alone. Over half of these facilities with recent violations are located within a three-mile radius of neighborhoods that are predominantly (over 75%) low-income and people of color.<sup>23</sup>



## In the last five years, the EPA took 15 formal and informal environmental enforcement actions at pharma plants in Puerto Rico.

Enforcement actions can range from informal warning letters and citations, to more formal and serious administrative orders and judicial action.<sup>24</sup> Here are a few examples of active and operating pharmaceutical manufacturing facilities that have received some of these formal enforcement actions for committing serious environmental violations:<sup>25</sup>

- PFIZER PHARMACEUTICALS in Barceloneta is violating the Lead and Copper rule (and has been continuously since 2020). The EPA established this regulation to control lead and copper in drinking water, as both cause health problems as mild as stomach distress, or as severe as learning disabilities and brain damage.<sup>26</sup> Pfizer has not addressed this issue.<sup>27</sup>
- AMGEN MANUFACTURING, LTD in Juncos has violated multiple Enforcement and Compliance environmental regulations over the past five years. From April 2019 to December 2020, they failed to submit their discharge monitoring report about chemicals they discharge. They also committed two coliform monitoring violations in 2021,<sup>28</sup> which means they failed to monitor for **pathogens** in their water treatment systems. The watershed near where Amgen operates, the Río Gurabo River and Ceiba Creek, has been found to be polluted with **ammonia, arsenic, phosphorus, selenium, and more,** which the EPA lists as potentially linked to Amgen and industrial discharge.<sup>29</sup>
- **THE BRISTOL MYERS SQUIBB** Manufacturing Company in Humacao violated the national standards for **hazardous air pollutants** in 2020.<sup>30</sup> They also failed to submit their discharge monitoring reports from April 2019 to September 2019, which the EPA requires of facilities that discharge pollutants into the waters. The EPA found that the watershed near where they operate, the Frontera Creek, suffered from **oxygen depletion** due to chemicals the manufacturing plant released into the water and also contained pathogens, which are dangerous to the endangered aquatic species in the creek.<sup>31</sup>
- >> All three companies constructed these manufacturing sites in areas with a high percentage of low-income households—over 70% low-income communities surrounding each pharma plant.<sup>32</sup>



#### HOW HAVE PHARMACEUTICAL CORPORATIONS BEEN ALLOWED TO CAUSE MASSIVE ENVIRONMENTAL DESTRUCTION WITH RELATIVE IMPUNITY?

For decades, community groups have sounded the alarm as the Puerto Rican government has prioritized the business interests of US multinationals (including lucrative tax breaks and lax regulations) over the environmental wellbeing of the island.

Since its inception, the Puerto Rican government has charged its Environmental Quality Board (EQB) with promoting economic development in PR "in accord with optimal environmental quality."<sup>33</sup> In practice, many of the so-called environmental regulators have either been beholden to industry interests or overridden by the government in the rare instances where they do not side with pharma.<sup>34</sup>

The US federal government also has a mixed track record on the issue of addressing the pharmaceutical sector's enormous pollution in Puerto Rico. While the EPA regulation of pharmaceutical manufacturing has improved since the 1970s and 80s, troubling loopholes still allow pharma corporations to evade essential rules. For example, though the FDA technically requires pharma corporations to do "an environmental assessment" on drug production, it often amounts to little more than a statement that the company anticipates no environmental impacts.<sup>35</sup> Significant cuts to EPA funding and staff, along with inconsistent investments in Puerto Rico, have resulted in the agency's failure to address the environmental emergencies fully.<sup>36</sup>

Although the pharmaceutical sector's lobbying of government officials has often focused on health, taxes, among other priorities,<sup>37</sup> some pharma giants use their influence on electeds to minimize environmental regulations. For instance, Johnson & Johnson recently lobbied around a bill to limit the use of harmful "forever" chemicals known as PFAS (which was eventually defeated by the US chemical lobby).<sup>38</sup> The US Navy testing has confirmed the US military released forever chemicals in Vieques, Puerto Rico, where some residents reportedly drink contaminated well water.<sup>39</sup>



Flooding in the wake of Hurricane Maria

## THE PHARMACEUTICAL SECTOR IS DEPLETING AND POLLUTING PUERTO RICO'S DRINKING WATER AND CRITICAL GROUNDWATER SUPPLIES

Groundwater pollution is currently one of the most disastrous environmental hazards faced by Puerto Rico. Toxic waste from pharma plants is a significant factor in this pollution and heavily impacts some communities' groundwater supplies.<sup>40</sup>

At times, Barceloneta on the Northern Coast has contained more than 60% of the island's groundwater supply.<sup>41</sup> Unfortunately, Barceloneta has also been home to over a half dozen pharma corporations, including Abbott and Bristol-Myers Squibb. The EPA has cited Barceloneta's Pfizer, Merck, and AbbVie manufacturing plants for violations of regulations, including the Safe Water Drinking Act and the Resource Conservation and Recovery Act (which regulates hazardous waste disposal).<sup>42</sup> Corporations like Abbott have used deep injection wells in Barceloneta, where untreated liquid waste is put directly into sinkholes or spread using sprinklers. These are incredibly hazardous because porous limestone aquifers cannot filter out toxins and are often close to wells that people use for drinking water. In describing Barceloneta's industrial area, the Environmental Quality Board cautioned that "the pathway from the point of contamination to the population [is] very short."<sup>43</sup>

In some cases, the pharma industry has also dumped liquid pharmaceutical waste directly into the Manatí River, which returned water into the aquifer, eventually reaching the ocean. As far back as the 1970s, fishermen in Puerto Rico identified an "odorous, thick, brown liquid" by factories like Merck's, which resulted in rivers developing vegetation and unpleasant smells as well as enormous declines in their fishing hauls.<sup>44</sup> The chemical waste impacted farmers as well, killing the cows and chickens on the banks of nearby rivers. The fishermen developed sores. One fisherman blamed the pharmaceutical companies: "Ever since the factories came, mounds of dead fish started appearing."<sup>45</sup> As a result of this pharmaceutical pollution, Puerto Rican communities face enormous health risks from unsafe drinking water. The archipelago has the worst rate of drinking water violations among any US state or territory.<sup>46</sup> Nearly 70% of Puerto Rico's water customers received tap water that violated federal health standards including illegally high levels of bacteria, harmful byproducts, and other contaminants in recent years.<sup>47</sup> A polluted water supply not only impacts individual households, but may pose serious risks to the food supply given many Puerto Rican farmers rely on groundwater to irrigate their crops.<sup>48</sup>

Because of improper and inconsistent water testing by Puerto Rico's water utility, PRASA, there is a lack of data tracking lead contamination levels in the water supply.<sup>49</sup> In the past, the EPA has issued steep fines to PRASA for failing to comply with the Clean Water Act and other safety requirements.<sup>50</sup>

>> A staggering 99.5% of Puerto Ricans are forced to rely on water systems that violate the Safe Drinking Water Act (as of 2015).51 Communities consumed toxic groundwater in the wake of Hurricane Maria: Puerto Ricans in Dorado, just outside San Juan, had no access to safe drinking water in the aftermath of Hurricane Maria. People drank hazardous well water from a Superfund groundwater contamination site.<sup>52</sup> According to the EPA, the site was polluted with industrial chemicals, including tetrachloroethylene and trichloroethylene, which "can have serious health impacts including damage to the liver and increasing the risk of cancer."<sup>53</sup> While the effects on Dorado residents remain unseen, studies have shown that drinking contaminated water from Superfund sites can contribute to elevated cancer risk.54 While the EPA has been unable to attribute the Superfund site to one specific source, the EPA has issued some enforcement actions to Dorado-based pharmaceutical manufacturing plants.<sup>55</sup>

Activists expressed concern that Superfund sites and landfills were flooded after Hurricane Maria, possibly contributing to chemical exposure and disease for future generations.<sup>56</sup> The EPA asserted that no contaminants had spread, but independent experts questioned their conclusions. Addressing these Superfund sites is all the more urgent considering that any natural disasters "aggravate and accelerate" the spread of pollutants from Superfund sites.<sup>57</sup> Proximity to Superfund sites, particularly those prone to flooding due to natural disasters, has since been found to decrease the life expectancy of local inhabitants by as much as 1.22 years.<sup>58</sup>

#### PHARMA IS DEPLETING SCARCE RESOURCES AS PUERTO RICO FACES A CLIMATE CRISIS

Pharma is not only polluting Puerto Rico's waterways; it is also depleting the scarce resource. Many of the archipelago's freshwater sources—including streams, lakes, and aquifers—are rapidly depleting.

While recent research is limited, past studies reveal times when pharmaceutical and chemical manufacturers took 7.38 million gallons of groundwater daily from Puerto Rico's largest aquifer on the North Coast. Drug companies were responsible for 37% of water withdrawals as of the year 2000.<sup>59</sup>

The increasingly severe effects of climate change compound Puerto Rico's groundwater depletion. Eighty-five percent of Puerto Ricans live within five miles of a coast. Rising sea levels (a projected 22 inches by 2060), and growing flooding and storm surges pose serious risks to the safety of Puerto Rican coastal towns. Climate change is also driving increasing droughts and food insecurity, severe tropical storms and hurricanes, coral reef die-offs, and other irreversible changes to the environment that pose grave threats to Puerto Ricans.<sup>60</sup> EPA designated Superfund sites in Puerto Rico are at major risk (but woefully unprepared) for flooding, storm surges, and other climate change-driven events.<sup>61</sup>

Rising sea levels and the rapid depletion of freshwater sources also threaten the long-term viability of the pharmaceutical sector's operations in Puerto Rico. The pharmaceutical sector will threaten to leave Puerto Rico if their lucrative tax breaks and preferential tax status is revoked.<sup>62</sup> In reality, it is more likely that the pharmaceutical sector's own unsustainable environmental practices trigger a pharma exodus from the archipelago.



Community members accessing drinking water in the wake of Hurricane Maria

## PHARMA POLLUTER: MERCK SHARP & DOHME IN BARCELONETA

Merck is responsible for nine EPA designated toxic Superfund sites around the United States in California, Pennsylvania, Virginia, New Jersey, Georgia, and Barceloneta, PR.<sup>63</sup> As recently as September 2021, the EPA cited the Merck facility in Puerto Rico for violations of the Safe Water Drinking Act and potential pathogens in drinking water. One hundred percent of the community surrounding this polluting Merck plant are people of color, with more than half living off less than \$15,000 per year.<sup>64</sup> The facility produces solvents, solid and sludge waste, and residues from incinerators.<sup>65</sup> While Merck's Barceloneta plant has emitted fewer categories of some air pollutants in the last decade, the emission of naphthalene has increased significantly since 2011.<sup>66</sup> According to the EPA, naphthalene is a "possible human carcinogen" that can cause liver damage and neurological damage in infants.<sup>67</sup>

Merck owns a long track record of slippery business deals designed to evade or profit off environmental regulations. As early as the 1970s, journalists reported that Merck was considering making chemicals for water treatment. This could be seen as an attempt to capitalize on growing government regulations on water pollution that would require increased purchase and use of those chemicals.<sup>68</sup> In the mid-gos, Merck reportedly entered into an agreement with the company P.S.E.&G to buy their "air pollution rights" in New Jersey. This deal would allow Merck to emit many additional tons of the chemicals that cause smog. While technically permitted, this practice speaks to the corporation's troubling commitment to environmental regulations.<sup>69</sup>

As Merck pollutes communities in Puerto Rico, its profits continue to skyrocket: their 2021 global revenue landed at \$47.9 billion.<sup>70</sup> Last year, as Merck transitioned from outgoing CEO Ken Frazier to incoming CEO Robert Davis, the company paid them a combined \$29M in total compensation.<sup>71</sup> Merck can more than afford to invest in adequate environmental protections to prevent future pollution at its facilities while funding critical remediation efforts to clean up the toxic sites it created.



## COMMUNITY EXPOSURE AND ADVERSE HEALTH OUTCOMES: LIVING NEXT TO TOXIC WASTE

Puerto Rican scientists and environmentalists have long alleged that the pharmaceutical industry was causing mercury poisoning, respiratory ailments, and cancer.<sup>72</sup> Dating back to the late 1960s, environmental groups like the Industrial Mission<sup>73</sup> realized that multinational companies were "responsible for the economic deterioration and environmental destruction" in Puerto Rico.

The groups collected stories from workers and researched the environmental and health impacts of the pharmaceutical industry on the surrounding communities.<sup>74</sup> Chemist and activist Dr. Neftalí García led the charge, testifying to the need for continued formal research about toxic exposure to chemicals, as he and his scientists observed a growing trend of high cancer rates and respiratory ailments in Puerto Rico. Dr. García also supported community opposition to pharma pollution in Manatí, Barceloneta and Cidra in the mid-seventies.<sup>75</sup> In some communities, like Arecibo, the hazardous waste left by pharmaceutical companies is just one of many dangerous environmental pollutants. Communities in Arecibo face continued impacts from the chemical manufacturing of agent orange, an illegal landfill, a failed sewage system, a paper mill full of asbestos, and a battery recycling company on top of a Pfizer-related hazardous waste site. Community members have asthma rates nearly twice the US average and suffer higher cancer rates than neighboring communities.<sup>76</sup>

From Barceloneta to Arecibo and from Vieques to Loíza, Puerto Rican communities around the archipelago face troublingly high cancer and asthma rates. The sheer scale and scope of industrial pollution in Puerto Rico make it challenging to differentiate what was fueled by the pharma sector versus the US military or other toxic industrial sites. However, the pharmaceutical sector undoubtedly contributes to this public health crisis.

#### **CANCER AND TOXIC WASTE**

Cancer accounted for 17.7% of all deaths of Puerto Rican residents in 2010.<sup>77</sup> Researchers have found that Puerto Rican residents are particularly vulnerable to increased cancer risk due to socioeconomic inequalities and under-resourced health care systems; health care access challenges are exacerbated by federal disenfranchisement in Puerto Rico's health care system and the ongoing government debt crisis.<sup>78</sup> Communities surrounding Superfund sites experience welldocumented increases in cancer rates, heart disease, and death, according to research in the US.<sup>79</sup> Children and babies who live near Superfund sites have higher rates of leukemia, seizures, learning disabilities, and central nervous system damage.<sup>80</sup>

In Puerto Rico, communities living on top of Superfund sites with pharmaceutical toxic waste have suffered from exposure to carcinogens. The EPA identified Pfizer as one of the "potentially responsible parties" for dumping toxic waste into the Vega Baja landfill, which is still on the National Priorities List.<sup>81</sup> People built houses directly on piles of toxic waste and "trash mounds" on the landfill site and were exposed to lead.<sup>82</sup>

While the EPA insisted that there was little cancer risk, the residents expressed concern about the cancer risk.<sup>83</sup> One Brisas del Rosario resident stated, "There has not been any importance given to health here. There are many people with conditions involving their skin, kidneys, and even cancer."<sup>84</sup> During the public comment, a man named Mario B. Perez from "Residents of Vega Baja Promoting Sustainable Environmental Development" (Vegabajeños Impulsando Desarrollo Ambiental Sustentable) expressed concern about the concentrations of trichloroethylene, a carcinogen, and the slow government response. He stated that the EPA could debate the costs and methodology of cleanup, but while residents waited for them to conclude their debate and implement cleanup measures, the toxic waste would contribute to cancer rates, while the lead poisoning exposure would cause learning problems for local children.<sup>85</sup>

The Barceloneta Landfill Site contains more than 300 tons of hazardous waste, which poses a cancer risk to the community members near the site.<sup>86</sup> In 1996, the EPA identified the following pharmaceutical companies as potentially responsible parties for collectively dumping hazardous waste into the Barceloneta Landfill:

- Abbott Laboratories
- E. I. du Pont de Nemours & Company
- Merck & Company, Inc.
- Roche Products, Inc.
- Schering Pharmaceuticals Corp.
- Sterling Pharmaceuticals Inc.
- Upjohn Manufacturing Co.<sup>87</sup>

A 1990 health risk assessment conducted by the US Agency for Toxic Substances and Disease Registry on the region reported that scientists had identified volatile organic compounds, including chloroform, toluene, phenols, and methylene chloride in samples of on-site water runoff and sludge. The water runoff and sludge also included aluminum, cobalt, iron, manganese, zinc, mercury, and lead.<sup>88</sup> Many of these are carcinogenic and deeply toxic.<sup>89</sup> The scientists determined that the site posed a risk to human health through direct contact and ingestion, inhalation of contaminants by residents, and even ingestion of fish that accumulated these contaminants. Unfortunately, the full government report is not publicly available, raising questions about whether the residents can access this information on potential health impacts.90

#### Troubling evidence continues to mount that US pharmaceutical and medical device operations in Puerto Rico may be contributing to high rates

of cancer. In August 2022, the Environmental Protection Agency warned people living near plants in Puerto Rico (along with 13 US states) that long-term exposure to the chemical ethylene oxide poses elevated risks of cancer, including breast cancer and lymphoma. The medical device cleaner is used on catheters, syringes, pacemakers, and other materials. Based on recent emissions data, the EPA reports that Puerto Rican communities are being exposed to the dangerous ethylene oxide in Añasco, Fajardo, Salinas and Villalba-in Fajardo and Salinas one in five people identify as Afro-Puerto Rican.<sup>91</sup> These areas are home to medical device sterilization plants. Puerto Rico has the largest number of sterilization facilities emitting this chemical out of any jurisdiction in the United States. According to the EPA's Caribbean Environmental Protection Division Director, Carmen Guerrero, "There are some communities where, due to long-term exposure to this gas, the risk is high. As this risk is too high, the communities have the right to be informed, and it is our duty to provide this new information that the EPA has."92 The EPA launched a public outreach campaign to reach communities who face the highest risk.93

#### GOVERNMENT INACTION FUELED BY ENVIRONMENTAL RACISM

Striking parallels can be seen with the treatment of low-income communities of color, particularly Black and Latino communities, in the United States who are more likely to live near Superfund sites and experience high rates of cancer.<sup>94</sup> Government response to toxic waste is slow and inadequate in low-income communities of color compared to wealthier neighborhoods which have serious ongoing health impacts.<sup>95</sup>

Puerto Rico has long faced disturbing trends of government inaction and poor health outcomes, the most famous being Vieques (an island off the eastern coast of Puerto Rico's main island, saturated with toxic metals where one in four community members are Afro-Puerto Rican). The federal government used Viegues as a military test range for six decades. They then abandoned it—and its residents.96 The island remains one of the most prominent examples of how the US government tried to cover the extent of the health damage to residents with cancer.<sup>97</sup> Puerto Rican communities face the added burden of "environmental colonialism," as the US government and US corporations extract, pollute, and profit off the archipelago's natural resources while Puerto Ricans have little recourse or formal power to address the environmental degradation and push for government action to hold polluters accountable for poisoning communities.98

#### ASTHMA AND RESPIRATORY ILLNESSES: A "MYSTERY?"

Roughly 14% of Puerto Ricans reported having asthma for part of their lives, nearly twice the rate of white people in the United States.<sup>99</sup> Still, some scientists have called this "alarmingly high rate of asthma" a "mystery," and "baffling,"<sup>100</sup> though this high rate has persisted for decades.<sup>101</sup>

Puerto Rican children are especially susceptible to developing respiratory illnesses that affect them throughout their life: a recent study shows that Puerto Rican children with an early-life respiratory illness would be more likely to develop asthma later. Scientists comparing Puerto Ricans living on the archipelago versus United States residents of Puerto Rican descent noted that the lower rates of developing asthma among US residents "may suggest an environmental effect associated with living in Puerto Rico that affects the prevalence of asthma."102 One recent study has shown that poor air quality, such as particulate matter in the air from pollution, increases asthma risk.<sup>103</sup> Because Puerto Ricans living on the archipelago suffer from asthma at a higher rate than Puerto Ricans in the Bronx<sup>104</sup>—and face higher asthma mortality rates than other demographic groups living in the US<sup>105</sup> the federal government must address the high environmental stressors on the island.

#### Pharmaceutical companies have violated the Clean Air Act in Puerto Rico, emitting hazardous chemicals into the air:

- In 2020, the EPA fined TAPI Puerto Rico (parent company TEVA Pharmaceuticals) over \$500,000 for allegedly violating the Clean Air Act at its plant in Guayama. The EPA identified emissions of 10 tons per year of acetonitrile, a hazardous air pollutant, and TAPI failed to produce a required toxic chemical release inventory report for its use of naphthalene. *Naphthalene* is a chemical that converts into a toxic vapor.<sup>106</sup>
- In 2016, the EPA fined Pfizer \$190,000 for failing to disclose hazardous chemical information at its plant in Barceloneta, violating the Clean Air Act. Pfizer used liquid ammonia and methylamine gas. Ammonia can irritate the respiratory tract and is highly corrosive.<sup>107</sup> Methylamine is highly flammable and harms the skin, respiratory tract, and eyes.<sup>108</sup>
- In 2014, the EPA fined Pfizer over \$300,000 for failing to have proper air pollution controls at the same Barceloneta plant. They risked leaking methylene chloride, an air pollutant that could cause dizziness, nausea, and liver damage. The EPA also found that Pfizer was failing to test its air pollution control equipment.<sup>109</sup>

#### **NEGATIVE IMPACTS ON MENTAL HEALTH**

Living in adverse environments negatively impacts the mental health of Puerto Ricans. A recent study showed that major depressive disorder and a history of at least one suicide attempt was associated with current asthma in adults, particularly older women, and pointed out the need for more research on housing conditions and air pollution as further contributing factors.<sup>110</sup> Another study named environmental stressors, including climate change and Hurricane Maria, as contributors to poor mental health.<sup>111</sup> In the immediate aftermath of the hurricane, many community members could not access the antidepressants and other psych medications they needed due to blocked roads and pharmacy and hospital closures. At the time, local psychologists worried about increased suicide rates.<sup>112</sup> By nine months after the hurricane, Puerto Rico's suicide rate had increased by 18% compared to the same period the prior year.<sup>113</sup>

#### PUERTO RICANS MAKE LIFE-SAVING MEDICINES... AND FACE SERIOUS OCCUPATIONAL EXPOSURE IN THE PROCESS

Pharmaceutical workers worldwide face dangers handling possibly toxic chemicals, hormones, and dangerous compounds. While there is a lack of detailed research on the health impacts of chemical exposure on Puerto Rico's pharmaceutical workers, a recent investigation by the Center for Popular Democracy and Hedge Clippers revealed the number of pharma Occupational Safety and Health Administration (OSHA) violations in Puerto Rico for the last ten years comprise the highest number of complaints, accident reports, or health and safety referrals in any US state or territory.<sup>114</sup> Exposure to potent chemicals, bacteria, and compounds can result in serious health hazards for people working in pharma plants. Pharmaceutical corporations must protect their workers accordingly.<sup>115</sup>

## CONSISTENT HAZARDS THAT PHARMACEUTICAL WORKERS FACE AROUND THE WORLD INCLUDE:



**Exposure to particles and dust leading to occupational asthma:** Nanotechnology, inhalable dust, and other chemical particles pose a risk for occupational asthma and other lung conditions.<sup>116</sup>



**Reproductive health side effects:** A 2014 study of women pharmaceutical workers in Iran found that exposure to mixtures of organic solvents was associated with increased menstrual disorders and hormonal changes among these workers.<sup>117</sup>



**Rashes and other skin conditions:** Touching certain types of spilled drugs or inhaling powder or foam in the workplace can lead to skin lesions and other itchy allergic reactions.<sup>118</sup>



**Increased cancer rates:** Studies among Nordic pharmaceutical workers found statistically significant risks for cancer, including significant lung, bladder, and breast cancer risks.<sup>119</sup>

In 1988, former employees of the Parke-Davis pharmaceutical factory in San Juan claimed that they suffered from work-related illnesses, "including cancerous cysts (requiring mastectomies), depression, headaches, and gastrointestinal disorders."120 They sued the company "on claims predicated on negligent failure to provide a safe workplace." As a result of exposure to hormones involved in the manufacture of oral contraceptives, "The injuries included loss of libido, depression, schizophrenia, dizziness, headaches, fibrocystic disease of the breasts, mastectomies, gastrointestinal disorders, gynecomastia and galactorrhea."121 They prevailed, and even though the corporation filed an appeal, the judge affirmed the initial ruling in favor of the workers.122

Since that legal case, few Puerto Rican workers have been able to secure legal remedies or hold US pharmaceutical corporations accountable for workplace chemical exposures. In 2005, Roberto Feliciano Rolon sued Ortho Biologics and OMJ Pharmaceuticals after a sodium metabisulfite spill at the manufacturing site where he worked. Even though he suffered from skin rashes, lesions, fever, and weakness, he eventually lost his case.<sup>123</sup> Among the approximately 80 OSHA enforcement actions at Puerto Rican pharma factories in the last decade, most resulted in no or low fines, even when workers became potentially exposed to harmful chemicals.<sup>124</sup>

## PHARMA'S DECADES OF OCEAN DUMPING: "900 BOEING 747'S WORTH OF WASTE"

The pharmaceutical industry in Puerto Rico is notorious for dumping its manufacturing byproducts and harmful toxins into the ocean. In 1972, pharmaceutical companies like Merck successfully pushed the EPA to establish the "Puerto Rico Dumpsite" (PRD), a 500-kilometer stretch of ocean north of Arecibo.<sup>125</sup> This dumpsite was initially framed as temporary and scheduled for disbanding after a new wastewater treatment opened; in reality, construction delays meant that the ocean dumping was permitted well into the early 1980s.

Many pharmaceutical corporations dumped waste into the ocean, including Bristol, Merck, Pfizer, Upjohn, and Abbott. As frequently as every few days, barges left the coast of Arecibo to dump chemicals into the ocean. While rules mandated the dumping start farther out at sea, some community members reported barges immediately releasing their toxic waste near the coasts.

The toxic waste totaled hundreds of thousands of metric tons. For instance, US pharmaceutical corporations dumped more than 387,000 tons of waste in the Puerto Rico trench between 1973 and 1978. That amounts to nearly 900 Boeing 747s worth of waste.<sup>126</sup>

The chemicals ranged from butanol, benzene, hydrocarbons, alcohols, and nitrogen compounds.<sup>127</sup> Pharmaceutical corporations released toxic chemicals like dimethyl aniline, "a highly toxic substance, particularly to blood, kidneys and liver, and it can be fatal if inhaled, swallowed or absorbed through the skin," off Puerto Rico's coast.<sup>128</sup> Water testing at the Puerto Rico dumping site found that dimethyl aniline remained in high concentrations for up to three days.<sup>129</sup>

#### THE HARMFUL AND LONG-TERM EFFECTS OF OCEAN DUMPING

Dumping sewage, pharmaceuticals, and low-level radioactive waste is no longer allowed. However, waste already released into PR's oceans can remain on the seafloor, posing ongoing risks.<sup>130</sup> The environmental impact of pharmaceutical waste is a critical but chronically understudied issue.

One scientific study from the 1980s found ocean dumping caused "demonstrable changes in the microbial community" in the ocean stretches used for toxic waste disposal by seven pharmaceuticals and one petrochemical plant.<sup>131</sup> Concerns about the ocean dumpsite prompted scientists to study the harmful effects of pharma pollution on fish. One study of PR's oceans found that no fish survived a 48-hour exposure to pharma waste at 5,000 parts per million.132 One study of shrimp-like amphipods in Puerto Rico's ocean found that exposure to pharma waste led to high mortality and low reproduction rates.133 In 2021, Puerto Rico's government declared an ecological state of emergency over large scale coral reef die-offs along the Northern and Southern coasts. Marine biologists have been unable to identify the pathogen responsible<sup>134</sup> and it remains to be seen whether long-term pharma ocean dumping has played a role in the emergency.

While a US Commerce study from 1983 argued that the "environmental costs of dumping pharmaceutical wastes were small,"<sup>135</sup> the same study noted a significant variation in phytoplankton's sensitivity to contamination and "sublethal" effects on animals.<sup>136</sup> The paper also indicated "it is clear that Upjohn and Bristol wastes were the most toxic with Upjohn waste exerting the more [sic] influence simply because it constituted about half the waste volume." The government study also documented the presence of N, N-dimethyl aniline in Bristol waste as a source of the high toxicity, despite arguing that this did not affect phytoplankton growth.<sup>137</sup>

#### THE RELEASE OF DRUGS INTO WATER SYSTEMS

The release of drugs into the ocean has potential impacts on marine wildlife like fish that could be considerable and a cause for alarm.<sup>138</sup> While there is little data on chemicals impacting Puerto Rico's marine life, studies of marine life off Southern Florida's coast have revealed exposure to high amounts of pharmaceuticals due to outdated water treatment facilities. A single fish in one study had sixteen different drugs in its system.<sup>139</sup> Pharmaceuticals used by humans and livestock (like cancer treatments and pain killers) have been found in water sources and may threaten marine life, given that these substances are sometimes carcinogenic and non-biodegradable.<sup>140</sup> According to a 2008 Associated Press investigation, "pharmaceutical residues had been detected in the drinking water of 24 major metropolitan areas across the country serving 41 million people; detected drugs included antibiotics, anticonvulsants, and mood stabilizers."141 In Puerto Rico, 10 of 14 drinking water samples taken around the island contained active pesticides and pharmaceuticals.142

Puerto Rico's toxic waste from the pharmaceutical sector poses unique challenges, and according to former EPA official Judith Enck, "They are all quite serious."<sup>143</sup>

## PHARMA IS DEPLETING PUERTO RICO'S SCARCE RESOURCES

#### PUERTO RICO'S FRAGILE POWER GRID

When Hurricane Maria hit Puerto Rico in 2017, the storm devastated the archipelago's already fragile power grid. A record-breaking 1.5 million customers were without power in the largest blackout in US history.<sup>144</sup> In the wake of Hurricane Maria, some US pharmaceutical operations, like AbbVie, were intact because they run on "independent power generation units."<sup>145</sup> While the pharma operations continued, many AbbVie employees living near their Jayuya plant struggled to get power nearly a year after the hurricane.<sup>146</sup> In the words of one pharma general manager, "Many people talked about how being here at work was not the reality—it was a luxury at the time [...] We had air-conditioning, we had communication, we had running water, hot food. And you can work. When people left to go back home, it was a different life."<sup>147</sup>

In addition to diesel generators, US pharmaceutical corporations reportedly relied on prison labor to repair storm damage to their facilities.<sup>148</sup> In Guayama, Pfizer used labor from people in a neighboring low-security detention center to fix the facility's broken fences. In exchange, the corporation reportedly allowed the prison to take drinking water from the manufacturing facility to the prison.<sup>149</sup> People in prisons around the island faced serious water and power outages and dangerous flooding post-Maria.<sup>150</sup> Although it was positive that people in the Guayama prison eventually secured access to drinking water, they should not have been required to give labor in exchange for a lifeline resource.

#### PHARMA'S 24/7 DIESEL GENERATOR EMISSIONS

In the wake of Hurricane Maria, most US pharmaceutical companies relied on backup generators to continue operations.<sup>151</sup> Industrial sites reportedly ran on diesel generators for months following the hurricane.<sup>152</sup> Amgen's Juncos site reportedly ran on diesel generators for over 120 days straight.<sup>153</sup>

Puerto Rico produces many life-saving or sustaining drugs and is the "sole source" for many vital medicines.<sup>154</sup> According to the Food and Drug Administration, around 40 critical medicines are solely or primarily produced by Puerto Ricans including HIV medications and injectable drugs. At the time of Hurricane Maria, 14 were "sole source" products not made anywhere else in the world.<sup>155</sup>

While the 24/7 use of diesel generators enabled the pharmaceutical factories to continue medicine production, there were still unintended health impacts on the surrounding communities.

#### THE HARMFUL IMPACT OF DIESEL GENERATORS

While many Puerto Rican communities and businesses rely on diesel generators, given the scale and scope of pharma's operations in Puerto Rico, pharmaceutical diesel emissions following Hurricane Maria are likely significant. The hurricane-damaged instruments used by the PR Environmental Quality Board to monitor air pollution and specific data on pharma are limited, but the widespread use of diesel generators did increase toxic air emissions in Puerto Rico.<sup>156</sup> Diesel generators pollute the air and contribute to many respiratory health issues.<sup>157</sup> Research has shown that "diesel exhaust contains more than 40 toxic air contaminants, including many known or suspected cancer-causing substances, such as benzene, arsenic, and formaldehyde. It also contains other harmful environmental pollutants, including nitrogen oxide, currently the single most important ozone-depleting emission."158 In the US, diesel exhaust is responsible for up to 70% of the cancer risk attributed to toxic air pollution.<sup>159</sup> In 2017, the Federal Emergency Management Agency (FEMA) warned Puerto Ricans that using generators could cause fires, electrocution, and carbon monoxide poisoning-but the federal agency did not mention the air pollution risks posed by diesel.<sup>160</sup>

#### **PHARMA-ONLY POWER PLANTS**

Hurricane Maria prompted many US pharmaceutical corporations to build or strengthen backup power systems. For instance, Mylan reportedly built its own power generation plant at the facility,<sup>161</sup> while Amgen invested \$40 million in a cogeneration plant following Hurricane Maria.<sup>162</sup> Many pharmaceutical corporations are creating their own power generation plants or microgrids and venturing into renewable energy sources like solar, wind, and ocean geothermal power.<sup>163</sup>

Many pharma corporations operating in Puerto Rico have committed to purchasing 100% of their electricity from renewable sources.<sup>164</sup> While this could potentially help reduce harmful industrial diesel emissions for Puerto Ricans, these initiatives will not fix Puerto Rico's struggling power grid or address longstanding issues with unreliable service, high costs, and vulnerability to climate change-driven catastrophic storm events. It also means that pharma corporations remain largely insulated from the harsh realities faced by Puerto Rican communities.<sup>165</sup>

Puerto Rico's energy grid received a D- rating from the American Society of Civil Engineers in 2019, and the fragile power grid has seen frequent blackouts.<sup>166</sup> A Government Accountability Office investigation found that as of July 2019 "neither FEMA [Federal Emergency Management Agency] nor HUD [United States Department of Housing and Urban Development] had funded long-term grid recovery projects in Puerto Rico," despite FEMA having obligated about \$5.7 billion by that time.<sup>167</sup> In June 2020, Puerto Rico's unelected and unaccountable Financial Oversight and Management Board (the FOMB), which Congress appointed, privatized the public electric utility and installed LUMA Energy, a joint venture half owned by Texas-based Quanta Services and Canadian oil/gas company ATCO, to provide the archipelago's power.<sup>168</sup> Puerto Rico's electric system relies heavily on fossil fuels like petroleum and coal. Only 3% of the electric grid comes from renewable energy.<sup>169</sup>

#### PHARMA'S HIGH GLOBAL CARBON FOOTPRINT >>

Globally, the pharmaceutical sector is fueling carbon emissions. Manufacturing medicines can be a carbon-intensive part of the pharmaceutical industry's supply chain.<sup>170</sup> For instance, making medicines causes 13% more carbon emissions than car manufacturers producing new cars—even though pharma's market share is nearly one-third smaller than the auto industry.<sup>171</sup>

## CORPORATE "GREENWASHING" BY PHARMA

Pharmaceutical corporations try to "brand" themselves as socially responsible and environmentally conscious. The term "corporate social responsibility" (CSR) has emerged as a responsibility "to do what's best not just for their companies, but people, the planet, and society at large."<sup>172</sup> Pharmaceutical corporations proudly declare their commitment to fighting climate change. While companies like Merck and Pfizer have committed to "carbon neutrality" in the next 5–8 years, it is unclear whether a reduction of carbon emissions will apply to or benefit Puerto Rico.<sup>173</sup> For instance, in 2021 Johnson & Johnson touted the company "expects that it will source the equivalent of 100% of the Company's electricity in the U.S. and Canada from wind and solar power by 2023," but added the caveat "based on current properties owned/leased by Johnson & Johnson within our operational control; *does not include Puerto Rico.*"<sup>174</sup> Pfizer which claims it is "committed to limiting environmental impact of discharges from manufacturing processes," recently secured funding to invest in "green" manufacturing operations in Singapore but no investments were made in Puerto Rico.<sup>175</sup> Similarly, Amgen publicized its "carbon neutrality" manufacturing goals, highlighting a sustainable Singapore facility and new sustainable Rhode Island, Ohio, and North Carolina facilities but made no mention of Amgen's 2,400 employees and 23 buildings in Puerto Rico.<sup>176</sup>

Pharmaceutical corporations that are publicly-traded must report to the US Securities and Exchange (SEC) Commission on their business activities. Some corporation's disclosures, like Abbott, indicate it is "potentially responsible" for superfund sites in Puerto Rico with clean up costs "not expected to exceed \$10 million."<sup>177</sup> It appears that other pharma corporations are failing to fully disclose the extent of their pollution in Puerto Rico and the climate-risks posed by their manufacturing footprint. For instance, Pfizer's SEC filings only include passing references to environmental issues: "We also are cleaning up environmental contamination from past industrial activity at certain sites" and the company has potential risks related to legal and settlement costs "related to actual or alleged environmental contamination."<sup>178</sup> However, Pfizer does not document the superfund sites it created in Barceloneta and Arecibo, nor the toxic dumping in the Vega Baja landfill.<sup>179</sup>

In scholar Alexa Dietrich's fieldwork in *The Drug Company Next Door* (2013), she found that while pharmaceutical corporations touted their commitment to CSR in Barceloneta, the "desires to limit legal liability... made it virtually impossible to substantively connect to, and to understand, community concerns." The response to concerns about ecological devastation and unhealthy water was often, "That is not our problem."<sup>180</sup>

Research on corporate greenwashing shows that organizations that make bold environmental claims hide the broader extent of the environmental damage they cause. A study found that over half of consumers surveyed believed that "greenwashed claims were a reliable source of information about a company's eco-practices."<sup>181</sup> Because greenwashing can be highly effective, independent assessment of corporate environmental practices is all the more urgent and necessary.



## **POLICY RECOMMENDATIONS**

#### The environmental devastation outlined throughout this report requires urgent action.

- Congress must hold hearings to investigate the pharmaceutical sector's environmental track record in Puerto Rico.
- The Environmental Protection Agency must move additional pharmaceutical pollution sites in Puerto Rico, such as Pfizer's Barceloneta facility and the Frontera Creek in Humacao, to the agency's "National Priorities List," while supervising robust clean up and remediation efforts at all Superfund sites on the archipelago.
- Puerto Rico's government must revoke the preferential tax status used by US pharmaceutical corporations operating in Puerto Rico if corporations continue to cause (and fail to address) widespread environmental devastation across the archipelago.
- The US Securities and Exchange Commission's (SEC) Climate and ESG Task Force<sup>182</sup> within the Division of Enforcement must investigate and identify environmental, social, and corporate governance-related misconduct consistent with potential violations including material gaps or misstatements in issuers' disclosure of climate risks under existing rules.<sup>183</sup>
- The SEC must also develop and enforce stronger ESG requirements to ensure that companies do not engage in "greenwashing."<sup>184</sup>
- Investors must hold pharmaceutical corporations accountable, including by using their proxy voting power<sup>185</sup> to oust directors who fail to exercise adequate oversight to live up to the companies' stated ESG commitments and potentially excluding non-compliant companies from ESG funds.

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#### **METHODOLOGY**

Facility violations were accessed via the EPA Enforcement and Compliance History Online (ECHO) database: <u>https://echo.epa.gov/facilities/facility-search?mediaSelected=all</u>. Records were narrowed down through "Geographic Location: Puerto Rico." To identify pharmaceutical manufacturing sites, the following North American Industry Classification System (NAICS) codes were used: 3254 (Pharmaceutical and Medicine Manufacturing), 32541 (Pharmaceutical and Medicine Manufacturing), and 325412 (Pharmaceutical Preparation Manufacturing). There are 54 active/operating pharmaceutical manufacturing facilities in Puerto Rico currently being reported on the ECHO database. The ECHO records included some medical device manufacturers which were included in the report's analysis, where noted. The ECHO database also included records for companies that fall outside pharmaceutical NAICS codes (for instance, companies in agribusiness, construction, and non-health related personal care products) so those were filtered out, where applicable, to ensure all compliance data highlighted in the report focused on the pharmaceutical sector.

To find sites with Formal Enforcement Actions due to environmental violations, we used the "Enforcement and Compliance" section to retrieve Formal Enforcement Actions within a date range of five years. The ECHO searchable database only provides enforcement action within the past five years.<sup>186</sup> According to the database, 15 sites in Puerto Rico had formal and/or informal EPA Enforcement Actions within the past 5 years. The ECHO database was also used to identify facilities with violations in the past three years, which totalled 18 facilities.

To find demographic information associated with the location of the pharmaceutical manufacturing site, we used the "Demographics" section to narrow down by "Percent People of Color (3-mile radius)" and "Percent Low Income (3-mile radius)." There are 33 pharmaceutical manufacturing sites located within a 3-mile radius where over 75% of the population are both people of color and low income.

Superfund site data was accessed via the EPA Superfund Enterprise Management System (SEMS) database. <u>https://cumulis.epa.gov/supercpad/CurSites/srchsites.cfm</u>. These records reflect both "active" and "archived" sites located in Puerto Rico and Region 2 (which includes NJ, NY, PR, VI) listed since the Superfund program was established.<sup>187</sup> "Active" sites are sites where remediation, assessment, removal, cost recovery, or other oversight actions are ongoing. "Archived" sites are sites where the EPA has determined that no further remedial actions are planned.<sup>188</sup> There are 520 "Active" and "Archived" sites total as of July 13, 2022. 279 are listed as "Active." Sites are named either by location (i.e., Vega Baja Landfill) or after the company deemed responsible. A total of 19 of these sites are named after the pharmaceutical (n = 15) or medical device manufacturing company (n = 4) that caused the toxic waste at each site.

Active sites on the National Priorities List (NPL) in Puerto Rico are available here: <u>https://www.epa.gov/superfund/national-priorities-list-npl-sites-state#PR</u>. There are currently 18 sites on the NPL in Puerto Rico.

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