## OF LIFE AND LIMB: THE FAILURE OF FLORIDA'S WATER QUALITY CRITERIA TO TEST FOR VIBRIO VULNIFICUS IN COASTAL WATERS AND THE NEED FOR ENHANCED CRITERIA, REGULATION, AND NOTIFICATION TO PROTECT PUBLIC HEALTH

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#### I. INTRODUCTION

The climate change debate has roared on for decades as scientists of the world argue that the oceans are rising and the world is warming, yet there remain individuals<sup>2</sup> who belittle the harrowing realities on the horizon.<sup>3</sup> These realities can no longer be ignored in the wake of climate events like Hurricane Katrina and Super Storm Sandy that battered the coasts of the United States in recent years, leaving behind billions of dollars in damage.<sup>4</sup> More recently, the year 2014 was declared the warmest year on record for both the land and ocean.<sup>5</sup> Scientists attribute this record warmth to the increase in temperature in the world's oceans,

<sup>2</sup> Florida Governor Rick Scott joined the ranks of those individuals attempting to deemphasize the grim realities that are forecasted by environmental scientists with his unwritten banning of the phrases "climate change" and "global warming" by officials in the state. Doyle Rice, *Fla. Gov. Bans the Terms Climate Change, Global Warming*, USA TODAY (Mar. 9, 2015), http://www.usatoday.com/story/weather/2015/03/09/florida-governor-climate-change-global-

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warming/24660287/ ("Sea-level rise was another term that Scott prohibited, saying it should be called 'nuisance flooding,' . . . ").

<sup>&</sup>lt;sup>3</sup> "By 2100 seas could rise as much as 6.6 feet," putting a significant portion of Miami-Dade County, Florida, underwater. "For every foot the seas rise, the shoreline would move inland 500 to 2,000 feet." The U.S. government's National Climate assessment has further predicted that "Florida will be battered in the coming decades by extreme weather—dry-season drought and rainy-season deluges" with rainy seasons being "stormier," hurricanes being "fiercer," and storm surges being "higher." Laura Parker, *Treading Water*, NAT'L GEOGRAPHIC, Feb. 2015, at 106, *available at* http://ngm.nationalgeographic.com/2015/02/climate-change-economics/parker-text. <sup>4</sup> *Hurricanes and Climate Change*, CENTER FOR CLIMATE AND ENERGY SOLUTIONS,

http://www.c2es.org/science-impacts/extreme-weather/hurricanes (last visited Apr. 17, 2015) ("Eight of the 10 costliest hurricanes on record in the United States have occurred since 2004. Hurricanes Katrina (2005) and Sandy (2012) were by far the most damaging, costing \$125 billion and \$65 billion respectively.").

<sup>&</sup>lt;sup>5</sup> These record highs are compared against recordings as collected since 1880. *State of the Climate: Global Analysis for Annual 2014*, NOAA NAT'L CLIMATIC DATA CENTER (Dec. 2014), http://www.ncdc.noaa.gov/sotc/global/2014/13.

easily one degree Fahrenheit higher than the global average.<sup>6</sup> While this increase may seem insignificant, increasing ocean temperatures have been directly associated with ocean stratification,<sup>7</sup> tropical cyclone activity,<sup>8</sup> and sea level rise.<sup>9</sup>

The nefarious duo of warming oceans and rising sea levels has created another menacing yet lesser-known climate change-induced problem: an increase in sea-borne diseases.<sup>10</sup> The oceans are a natural host of many bacteria, including one lurking culprit—Vibrio vulnificus, a bacterium that dwells along the coasts of the United States, most notably in the tepid waters of the Gulf of Mexico, including Florida's Gulf Coast.<sup>11</sup> Vibrio vulnificus can lead to disease in those unlucky enough to encounter it, either by contact between the bacteria and an open wound exposed to seawater or through consumption of contaminated seafood.<sup>12</sup> Most healthy individuals who come into contact with the bacteria may have no side effects from the exposure at all or suffer from "vomiting, diarrhea, and abdominal pain," while individuals considered to be immunocompromised may face an infection of the bloodstream that causes "a severe and life-threatening illness characterized by fever and chills, decreased blood pressure (septic shock), and blistering skin lesions."<sup>13</sup> For example, the worst case scenario

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> Ocean stratification is the failure of nutrient-rich surface layers of the ocean to mix with the underlying deep layer of the ocean, caused by excess heat the oceans are absorbing. The direct result of this phenomenon is a reduction in phytoplankton, a major player in the marine ecosystem, as this organism supports the existence of many zooplankton communities that are the basis for many major fisheries. Randall S. Abate & Sarah Ellen Krejci, *Climate Change Impacts on Ocean and Coastal Law: Scientific Realities and Legal Responses, in* CLIMATE CHANGE IMPACTS ON OCEAN AND COASTAL LAW 1, 9 (Randall S. Abate ed., 2015).

<sup>&</sup>lt;sup>8</sup> *Id.* at 10 (discussing the increase of "tropical cyclone duration, intensity, and frequency" as the ocean temperatures continue to rise).

<sup>&</sup>lt;sup>9</sup> Sea Level Rise, NAT'L GEOGRAPHIC, http://ocean.nationalgeographic.com/ocean/critical-issuessea-level-rise/ (last visited Apr. 17, 2015) (attributing the rise in sea levels to three major contributors: warmer oceans, accounting for about half of the sea level rise in the past century; melting of the polar ice caps and glaciers as temperatures get increasingly higher and winters cool less; and melting of the ice sheets covering Greenland and Antarctica).

<sup>&</sup>lt;sup>10</sup> Robin Kundis Craig, *A Public Health Perspective on Sea-Level Rise: Starting Points for Climate Change Adaptation*, 15 WIDENER L. REV. 521, 532 (2010). <sup>11</sup> *Id.* at 533.

<sup>&</sup>lt;sup>12</sup> Vibrio Vulnificus, CENTERS FOR DISEASE CONTROL & PREVENTION,

http://www.cdc.gov/vibrio/vibriov.html (last updated Oct. 21, 2013).

 $<sup>^{13}</sup>$  Id. (finding cases of bloodstream infection to be fatal "about 50% of the time").

occurred for a man on a fishing trip when a cut on his leg came into contact with Gulf water in Estero Bay in Fort Myers, Florida.<sup>14</sup> He was dead within hours.<sup>15</sup>

While the Gulf states are the usual candidates for Vibrio illnesses,<sup>16</sup> the increase in global ocean temperatures has led to cases of Vibrio vulnificus being reported along the Atlantic coast in states as unlikely as Rhode Island, Delaware, and New Jersey, and even more remote are the cases being reported in Israel.<sup>17</sup> As water temperatures around the globe continue to rise, Vibrio bacteria will continue their journey into new oceans and coastal areas.<sup>18</sup> A 2012 study conducted in the Baltic Sea suggests that every one degree increase in sea surface temperature doubles the number of observed cases of Vibrio vulnificus.<sup>19</sup> Thus, the one-degree Fahrenheit increase in global sea temperatures that has already occurred<sup>20</sup> could lead to the doubling of Vibrio vulnificus illnesses. This potential increase in the number of illnesses is significant, especially given that the disease is often unrecognized and underreported and, with warming waters, has the potential to move up the coasts to regions where health professionals are less familiar with its risks.<sup>21</sup>

For most, the biggest concern when diving into the ocean is a possible, though exceedingly rare, shark encounter; however, it is the unexpected, unseen risk of Vibrio vulnificus that poses the greater danger. Part I of this paper discusses Vibrio vulnificus cases along the coasts of Florida, examining both the

<sup>&</sup>lt;sup>14</sup> Haley Hinds, *Winter Haven Man Contracts Deadly Vibrio Vulnifius Bacteria*, Fox 13 (Oct. 5, 2015), http://www.fox13news.com/news/local-news/30408592-story.

<sup>&</sup>lt;sup>15</sup> *Id.* 

<sup>&</sup>lt;sup>16</sup> *Vibrio Vulnificus, supra* note 12.

<sup>&</sup>lt;sup>17</sup> Craig, *supra* note 10, at 533.

<sup>&</sup>lt;sup>18</sup> Nina Chestney, *Bacteria Outbreak in Northern Europe Due to Ocean Warming, Study Says*, REUTERS (July 22, 2012), http://www.reuters.com/article/2012/07/22/us-climate-oceans-bacteria-idUSBRE86L0ET20120722 (stating that, though Vibrio tends to prefer warmer tropical marine environments, global ocean warming is allowing Vibrio to thrive in regions where it could not survive in the past, including Chile, Peru, and Spain).

<sup>&</sup>lt;sup>19</sup> Craig Baker-Austin et al., *Emerging Vibrio Risk at High Latitudes in Response to Ocean Warming*, NATURE CLIMATE CHANGE, July 22, 2012, at 73, 75.

<sup>&</sup>lt;sup>20</sup> State of the Climate, supra note 5.

<sup>&</sup>lt;sup>21</sup> Vibrio Parahaemolyticus, CENTERS FOR DISEASE CONTROL & PREVENTION,

http://www.cdc.gov/vibrio/vibriop.html (last updated Oct. 21, 2013) (noting that infections caused by Vibrio species only "became nationally notifiable in 2007").

illnesses that were contracted through exposure of open wounds to seawater and those contracted through the consumption of raw oysters from the Gulf Coast. This part also emphasizes the overwhelming lack of warning that individuals who contracted Vibrio-related illnesses received concerning the risks of the bacteria in Florida's coastal waters. Part II analyzes existing federal and state regulations regarding water quality along the coasts, including regulatory bodies that have sprung into existence to combat water quality issues and the procedures used to test coastal waters for the presence of bacteria. It also addresses the regulations governing shellfish harvesting and consumption, from Florida's cooperation with the National Shellfish Sanitation Program (NSSP) to consumer advisories that are now mandated by the state. Part II concludes with a discussion of the procedure for warning the public of Vibrio along the coasts.

Part III introduces the stringent regulation of raw oyster sales and consumption in California and the effect these regulations have had on reported cases of raw oyster-associated illness from Vibrio bacteria. Part IV proposes several methods by which existing laws and regulations could be amended or enhanced to better protect the public against the risk posed by Vibrio vulnificus. One method involves adding Vibrio vulnificus to the current bacteria criteria for water quality as a possible source of impaired waters in Florida, requiring enhancement of Florida's Beach Water Sampling Program's testing of bacterial levels along the coast to include a process that isolates Vibrio bacteria. Another proposed method suggests implementing regulations similar to those in California to warn more individuals of the bacteria's risks, and likely reduce the number of oyster-related Vibrio cases. The final proposed method involves creating a process by which Florida can notify and warn the public of the presence of Vibrio vulnificus in its waters and food using the existing systems of public notification already in place for other forms of bacteria.

#### II. THE IMPACT OF VIBRIO VULNIFICUS ON FLORIDA'S COASTS

Vibrio bacteria are varied and include those causing cholera, as well as Vibrio vulnificus's more mild relation Vibrio parahaemolyticus.<sup>22</sup> These bacteria are found in warm surface waters with high salinities, and are most commonly present in the summer and early fall.<sup>23</sup> Thus, Vibrio vulnificus is a natural presence along Florida's Gulf Coast due to the Gulf's warm surface temperatures and salinity.<sup>24</sup> Because the bacteria is a natural occurrence,<sup>25</sup> it often gets little attention until it is too late. Of the Gulf States reporting Vibrio vulnificus infections, "Florida has reported the majority of the cases," with an average of fourteen a year since 1981.<sup>26</sup> The number of reported cases of Vibrio vulnificus infection has generally increased each year,<sup>27</sup> and this increase is largely attributed to climate change. As the world warms, the oceans warm, and as the oceans warm, so grows the Vibrio bacteria population.<sup>28</sup> From 2008 to December of 2014, Florida's Department of Health recorded 207 cases of Vibriosis caused

<sup>&</sup>lt;sup>22</sup> *Vibrio*, MARYLAND HEALTHY BEACHES, http://www.marylandhealthybeaches.org/vibrio.html (last visited Jan. 23, 2016). Vibrio parahaemolyticus is found in brackish saltwater and is known to cause gastrointestinal illness. It is more commonly contracted through consumption of seafood, and illness through exposure is considered rare, unlike its relative Vibrio vulnificus. Diarrhea and abdominal cramping are generally the worst symptoms reported, and most cases clear up within three days. *See Vibrio Parahaemolyticus, supra* note 21.

<sup>&</sup>lt;sup>23</sup> *Id*.

<sup>&</sup>lt;sup>24</sup> Information on Vibrio Vulnificus, FLA. DEP'T OF HEALTH ONLINE NEWSROOM (Sept. 1, 2014), http://newsroom.doh.state.fl.us/2014/09/01/information-on-vibrio-vulnificus/ (noting that vibrios are known as "'halophilic' because they require salt'').

<sup>&</sup>lt;sup>25</sup> When a biology professor who studied Vibrio vulnificus was asked about the bacteria, he simply stated: "It's normal flora in the water . . . It belongs there." *Deadly Bacteria Vibrio can Kill with Little Warning*, CBS NEWS (Oct. 24, 2013), http://www.cbsnews.com/news/deadly-bacteria-vibrio-can-kill-with-little-warning/ (quoting Dr. James Oliver, professor of biology at the University of North Carolina).

<sup>&</sup>lt;sup>26</sup> Carina Blackmore, *Vibrio Vulnificus*, FLA. DEP'T OF HEALTH (Oct. 26, 1999), http://www.floridahealth.gov/diseases-and-conditions/vibrio-infections/\_documents/Vibrio-vulnificus.pdf.

<sup>&</sup>lt;sup>27</sup> There were fifteen reported Vibrio vulnificus cases in 2008, twenty-four in 2009, thirty-two in 2010, thirty-five in 2011, twenty-seven in 2012, forty-one in 2013, and thirty-three in 2014. *Information on Vibrio Vulnificus, supra* note 24.

<sup>&</sup>lt;sup>28</sup> Enjoy the Water, but be Smart and Avoid the Vibrios, GULF COAST RES. LABORATORY, http://www.usm.edu/gcrl/microbiology/vibrio.vulnificus.threat.via.wounds.php (last visited Apr. 17, 2015) ("The rising water temperatures promote the increase in Vibrio vulnificus not only in our own coastal waters. New cases of the bacterium are being found in waters where they were not previously perceived as a threat.").

by encounters with Vibrio vulnificus.<sup>29</sup> Of the 207 reported cases in the past 6 years, 63 resulted in fatalities.<sup>30</sup>

The Gulf of Mexico is not the only hotbed of Vibrio vulnificus infection, as cases are being reported more often along the Atlantic Coast and in Northeast Florida.<sup>31</sup> These figures, however, may not reflect the true percentage of infections that are contracted in Florida, as the state's beaches draw a number of tourists from around the nation, and oysters are shipped from the state. The sandy beaches and numerous raw shellfish bars along Florida's extended miles of coast make this state prone to both methods of contracting the Vibrio vulnificus infection, via seawater exposure and raw oyster consumption.

# A. Wound Infections Resulting from Exposure to Vibrio Vulnificus via Seawater

A commonly touted piece of wisdom is that swimming in the salty waters of the ocean will help heal any minor wounds an individual may sustain. This turns out to be wildly inaccurate for some individuals who stumble upon Vibrio vulnificus while swimming with even a minor wound like a blister.<sup>32</sup> Wound infections resulting from Vibrio exposure account for sixty percent of reported cases of the illness in the United States,<sup>33</sup> but only about thirty percent of the reported cases in Florida.<sup>34</sup> While the bacteria does not have quite the "flesheating" effect that has been attributed to it, it does make for some terrifying and lethal injuries when it invades an open wound. Health officials and Florida health agencies have waged a battle with the media—who refer to Vibrio vulnificus outbreaks along the coast as "flesh-eating" bacteria—to stop using the term, which is generally used to refer to the condition known as necrotizing fasciitis<sup>35</sup>

<sup>&</sup>lt;sup>29</sup> Information on Vibrio Vulnificus, supra note 24.

<sup>&</sup>lt;sup>30</sup> *Id*.

 $<sup>^{31}</sup>$  Deadly Bacteria, supra note 25.

<sup>&</sup>lt;sup>32</sup> Jeff Skrzypek, *Dangerous Bacteria: Vibrio Vulnificus in Florida Ocean Hospitalizes 13, Kills 3,* ABC ACTION NEWS (Aug. 6, 2014), http://www.abcactionnews.com/news/state/flesh-eating-bacteria-vibro-vulnificus-in-florida-ocean-hospitalizes-32-kills-10.

<sup>&</sup>lt;sup>33</sup> Enjoy the Water, supra note 28.

<sup>&</sup>lt;sup>34</sup> Blackmore, *supra* note 26.

<sup>&</sup>lt;sup>35</sup> Necrotizing fasciitis is the scientific name for the bacterial infection that "spreads rapidly and destroys the body's soft tissue" and that the media has dubbed "flesh-eating." This bacterial

that can be caused by multiple types of bacteria.<sup>36</sup> Vibrio vulnificus entering an open wound does have the effect, however, of painful cellulitis,<sup>37</sup> localized tissue swelling, and hemorrhagic bullae<sup>38</sup> in most patients, while the more severe cases may develop into necrotizing fasciitis.<sup>39</sup> Vibrio vulnificus will have little, if any, effect on healthy individuals, but may ravage the bodies of immunocompromised individuals.<sup>40</sup>

Once a wound has been exposed to Vibrio vulnificus by introduction to seawater, the bacteria acts quickly to claim the surrounding tissues as its own.<sup>41</sup> An example of a worst case scenario Vibrio vulnificus infection is the tragic death of Henry "Butch" Konietzky in September of 2013.<sup>42</sup> While fishing in the Atlantic Intracoastal Waterway near Ormond Beach, Mr. Konietzky, who had no reported health problems or open wounds of which his wife was aware, encountered Vibrio vulnificus and was none the wiser until he noticed a purple lesion on his ankle the

http://www.mayoclinic.org/diseases-conditions/cellulitis/basics/definition/CON-20023471. <sup>38</sup> These blisters often appear on the limbs and can quickly evolve into necrotizing fasciitis. Gun-Wook Kim et al., *Bullae and Sweat Gland Necrosis in the Differential Diagnosis for Vibrio Vulnificus Infection in an Alcoholic Patient*, J. OF KOREAN MED. SCI. (Feb. 25, 2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3051097/.

infection is not only caused by Vibrio vulnificus, but can result from infections of group A strep, E. coli, Clostridium, and several others. The infecting bacteria produce toxins that destroy the tissue they are infecting, causing the tissue to die. The bacteria mainly attack tissues surrounding the body's blood vessels, muscles, fat, and nerves, known as the *fascia*. *Necrotizing Fasciitis: A Rare Disease, Especially for the Healthy*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/Features/NecrotizingFasciitis/index.html (last updated June 28, 2013). <sup>36</sup> Chris Olwell, *DOH: Vibrio Not 'Flesh-Eating Disease'*, THE NEWS HERALD (July 31, 2014), http://www.newsherald.com/news/health/doh-vibrio-not-flesh-eating-disease-1.353202?page=0

<sup>(</sup>quoting Sheri Hutchinson, Florida Department of Health press secretary, as saying, "[V]ibrio is not a flesh-eating virus.").

<sup>&</sup>lt;sup>37</sup> "Cellulitis appears as a swollen, red area of skin that feels hot and tender, and it may spread rapidly." *Diseases and Conditions: Cellulitis*, MAYO CLINIC (Feb. 23, 2012),

<sup>&</sup>lt;sup>39</sup> Michael H. Bross et al., *Vibrio Vulnificus Infection: Diagnosis and Treatment*, AM. FAM. PHYSICIAN (Aug. 15, 2007), http://www.aafp.org/afp/2007/0815/p539.pdf.

<sup>&</sup>lt;sup>40</sup> *Vibrio Vulnificus, supra* note 12 ("Among healthy people, ingestion of V. *vulnificus* can cause vomiting, diarrhea, and abdominal pain. In immunocompromised persons, particularly those with chronic liver disease, V. *vulnificus* can infect the blood stream, causing a severe and life-threatening illness . . .."). *See also Enjoy the Water, supra* note 28 (reporting that immunocompromised individuals are eighty times more likely to develop a bloodstream infection

after Vibrio vulnificus exposure than healthy individuals).

<sup>&</sup>lt;sup>41</sup> *Enjoy the Water, supra* note 28 ("Vibrio wound infections happen fast; symptoms may become evident in only four hours.").

<sup>&</sup>lt;sup>42</sup> Deadly Bacteria, supra note 25.

same night of his fishing trip.<sup>43</sup> Mr. Konietzky and his wife, Patty, thought little of the lesion at first, brushing it off as a spider bite, but by the next day, Mr. Konietzky was reporting painful burning near the wound and the lesion began spreading.<sup>44</sup> Mrs. Konietzky took her husband to the hospital, where she was informed that he had a blood infection; it took only sixty-two hours from exposure for Vibrio vulnificus to claim Mr. Konietzky as its victim.<sup>45</sup> This example is a worst case scenario of a wound infection for several reasons, one of which is the resulting fatality, because wound infections are reported as having only an eleven percent mortality rate.<sup>46</sup> More striking is the fact that Mr. Konietzky appeared to be, for all intents and purposes, healthy; his wife did not report him as being immunocompromised.<sup>47</sup>

All Florida cases of Vibrio vulnificus do not end so tragically, but each case does leave the victim with a reminder of the lurking dangers along Florida's coasts. Eighty-four-year-old Margaret Freiwald, considered relatively healthy by her family with her only reported ailment being arthritis, encountered the bacteria while swimming in the Gulf of Mexico between the Bayport and Hernando channels.<sup>48</sup> Ms. Freiwald scraped her shin in her effort to get back into the boat that she and her group had taken into the Gulf, but no problem appeared until later that night, when she noticed that the wound began to look infected.<sup>49</sup> Three days after the minor scrape, Ms. Freiwald had her leg amputated above the knee.<sup>50</sup>

<sup>&</sup>lt;sup>43</sup> Id.

<sup>&</sup>lt;sup>44</sup> *Id.* <sup>45</sup> *Id.* 

<sup>&</sup>lt;sup>46</sup> Blackmore, *supra* note 26.

<sup>&</sup>lt;sup>47</sup> Deadly Bacteria, supra note 25. Compare [Cf.] Stephanie Genuardi, Warm-Water Ocean Bacteria can be Life-Threatening, SUN SENTINEL (July 23, 2010), http://articles.sunsentinel.com/2010-07-23/health/fl-mystery-bacteria-20100723 1 bacteria-vibrio-septic-shock (reporting the death of Shirley Malavenda, an eighty-six-year-old who went swimming with a small scrape on her leg in Miami-Dade in Matheson Hammock Park and was rushed to the hospital four days later, where her leg was amputated. She died in the hospital one month later, never to recover from her battle with the bacteria.).

<sup>&</sup>lt;sup>48</sup> Margaret Freiwald: Vibrio Vulnificus Bacteria in the Gulf Causes Infection, Woman has Leg Amputated, FIRST COAST NEWS (Aug. 2, 2013),

http://www.firstcoastnews.com/news/article/322319/1/Margaret-Freiwald-Vibrio-vulnificusbacteria-in-the-Gulf-causes-infection-woman-has-leg-amputated. <sup>49</sup> Id.

<sup>&</sup>lt;sup>50</sup> Id. See also Liz Freeman & Kristine Gill, Health Officials: Nothing Wrong with SWFL Water Despite Cases of Deadly Infections, NAPLES DAILY NEWS (Aug. 13, 2013),

Thirteen-year-old Jacob Ahler was scalloping with his family in the Gulf of Mexico when he got a splinter while unloading the boat.<sup>51</sup> His family treated the wound as normal, cleaning it and putting antiseptic cream on the injury, but by the next morning his foot had swollen to nearly triple its normal size and was burning hot to the touch.<sup>52</sup> His test results at the hospital confirmed a Vibrio vulnificus infection.<sup>53</sup> Jacob's foot was saved by the timely diagnosis and administration of antibiotics provided by his doctors.<sup>54</sup> While Vibrio vulnificus does not always end in fatality, the bacteria leaves a mark on those who have had the misfortune of encountering it.<sup>55</sup>

The above cases are just a few examples of the 207 that have been reported in the past 6 years in Florida's warm, coastal waters.<sup>56</sup> As the global climate warms and the oceans follow suit, Vibrio vulnificus will grow in number and claim new victims. It is important in this time of increasing cases and regional spread of Vibrio vulnificus that individuals are apprised of the danger the bacteria poses, as many treating physicians in new regions may have little experience with the bacteria and immediate treatment for the bacteria makes the difference between the worst and best case scenarios.<sup>57</sup> For now, the Florida Department of Health warns individuals to avoid exposing broken skin or open wounds to warm

http://www.naplesnews.com/news/state/health-officials-nothing-wrong-with-swfl-water (noting that Vibrio vulnificus impacts the elderly, not just the immunocompromised, at a higher degree and covering the recovery of Ms. Freiwald after her amputation).

 <sup>&</sup>lt;sup>51</sup> Jennifer Titus, 2 Cases of Flesh Eating Bacteria in Sarasota, 10 NEWS (July 31, 2014), http://www.wtsp.com/story/news/health/2014/07/30/flesh-eating-bacteria-florida/13353945/.
 <sup>52</sup> Id.

 $<sup>^{53}</sup>$  *Id*.

<sup>&</sup>lt;sup>54</sup> Alex DeMetrick, *Experts Warn About Flesh-Eating Bacteria in Chesapeake Bay*, CBS BALTIMORE (July 31, 2014), http://baltimore.cbslocal.com/2014/07/31/experts-warn-about-vibrio-infection-in-chesapeake-bay/ (referring to Jacob Ahler's case as an example of the need for immediate treatment when Vibrio vulnificus infections are expected).

<sup>&</sup>lt;sup>55</sup> Amber Castleman, daughter of eighty-four-year-old Vibrio victim Margaret Freiwald, told the media that she didn't think she would ever swim again after watching her mother struggle with the bacteria that subsequently caused the amputation of her leg. *Margaret Freiwald*, *supra* note 48. <sup>56</sup> *Information on Vibrio Vulnificus*, *supra* note 24.

<sup>&</sup>lt;sup>57</sup> Enjoy the Water, supra note 28 ("A Vibrio vulnificus infection can be tricky to diagnose and treat. And many clinicians and physicians have not seen a case first-hand.").

coastal or brackish waters as the best means of avoiding infection from exposure to the bacteria.<sup>58</sup>

# B. Consuming Shellfish in Months Not Containing an "R" – Contracting Vibrio Illnesses from Eating Raw Shellfish from Florida's Gulf Coast

According to the United States Food and Drug Administration (FDA), Vibrio vulnificus is the leading cause of death in the United States resulting from shellfish consumption.<sup>59</sup> These deaths are largely attributed to raw oysters from the Gulf of Mexico.<sup>60</sup> Vibrio vulnificus is especially hard to detect in oysters, making the bacteria hard to regulate, because the bacteria does not change the taste, odor, or appearance of the shellfish.<sup>61</sup> One reliable method to eliminate the risk of the bacteria is heat.<sup>62</sup> The CDC recommends boiling a shelled oyster until it opens to ensure that the risk of bacteria is eliminated.<sup>63</sup> The fact remains, however, that many individuals still enjoy eating raw oysters, so much so that popular myths have sprouted from the warnings of the food item's risks to give these individuals a false sense of security when consuming the raw shellfish. One of the most popular, and only partially correct, myths is that oysters are safe to consume so long as the month in which they are consumed contains an "r."<sup>64</sup> While it has been proven that the Vibrio vulnificus population is more prevalent in the warmer summer months of May, June, July, and August, an overwhelming

<sup>&</sup>lt;sup>58</sup> Information on Vibrio Vulnificus, supra note 24.

<sup>&</sup>lt;sup>59</sup> Nicholas A. Daniels, *Vibrio Vulnificus Oysters: Pearls and Perils*, 52 CLINICAL INFECTIOUS DISEASES 788, 788 (2011), *available at* http://cid.oxfordjournals.org/content/52/6/788.long.

<sup>&</sup>lt;sup>60</sup> Charles A. Kaysner & Angelo DePaola, Jr., *Vibrio, in* BACTERIOLOGICAL ANALYTICAL MANUAL 9 (8th ed. 2004), *available at* 

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070830.htm ("V. *vulnificus* causes septicemia and death following ingestion of seafood . . ..").

<sup>&</sup>lt;sup>61</sup> Vibrio Vulnificus, supra note 12.

<sup>&</sup>lt;sup>62</sup> Vibrio Vulnificus Health Education Kit Fact Sheet, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm085365.htm (last updated Nov. 26, 2014).

<sup>&</sup>lt;sup>63</sup> *Information on Vibrio Vulnificus, supra* note 24 ("For shellfish in the shell, either a) boil until the shells open and continue boiling for 5 more minutes, or b) steam until the shells open and then continue cooking for 9 more minutes. Do not eat those shellfish that do not open during cooking.").

<sup>&</sup>lt;sup>64</sup> Raw Oyster Myths, U.S. FOOD & DRUG ADMIN.,

http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm085385.htm (last updated Nov. 26, 2014).

forty percent of Vibrio vulnificus cases are reported in the colder months from September through April, thus leaving no truly safe month for raw oyster consumption.<sup>65</sup>

The bulk of Florida's reported cases of Vibrio vulnificus infection result from the consumption of raw shellfish.<sup>66</sup> Infection from ingestion of the bacteria through oysters normally ranges from mild gastroenteritis<sup>67</sup> to the more severe cases of primary septicemia,<sup>68</sup> which has a mortality rate of more than fifty percent.<sup>69</sup> Gastroenteritis is the likely outcome of a healthy individual encountering Vibrio vulnificus in a raw oyster, while groups considered at risk<sup>70</sup> are the likely candidates for septicemia.<sup>71</sup> Since 1997, 110 cases of Vibrio vulnificus resulting from oyster consumption have been reported by individual Florida counties.<sup>72</sup>

<sup>&</sup>lt;sup>65</sup> *Id.* (dispelling other oyster myths such as hot sauce and alcohol having the ability to kill bacteria found in the shellfish and that oysters only contain Vibrio vulnificus if cultivated from polluted waters).

<sup>&</sup>lt;sup>66</sup> A study of Florida Vibrio vulnificus cases from 1981, when reporting began, to 1993 showed that over half (fifty-three percent) of the cases reported were from ingestion of raw oysters. Blackmore, *supra* note 26.

<sup>&</sup>lt;sup>67</sup> "Gastroenteritis is characterized by complaints (in descending order of frequency) of abdominal pain or cramps, nausea, vomiting, diarrhea, fever, and chills." Michael A. Horseman & Salim Surani, *A Comprehensive Review of Vibrio Vulnificus: An Important Cause of Severe Sepsis and Skin and Soft-Tissue Infection*, 15 INT'L J. INFECTIOUS DISEASES, no. 3, Mar. 2011, at 157, 161-62.

<sup>&</sup>lt;sup>68</sup> Primary septicemia is marked by reports of nausea, vomiting, abdominal pain, fever, chills, and, in some instances, necrotic ulcers. In many, this illness will progress into septic shock, or extraordinarily low blood pressure, and in more than half of the cases, as stated above, the final stage of the illness is death. Some patients have even reported mental status changes like lethargy or disorientation. *Id.* 

<sup>&</sup>lt;sup>69</sup> *Id.* at 162.

<sup>&</sup>lt;sup>70</sup> The FDA includes in the group of high-risk individuals for septicemia those suffering from disease of the liver (like cirrhosis or hepatitis), diabetes, cancer, iron overload disease (hemochromatosis), alcoholism, and any other illness which may cause an individual to be immunocompromised, like HIV. *Fact Sheet, supra* note 62.

<sup>&</sup>lt;sup>71</sup> Horseman & Surani, *supra* note 67, at 162.

<sup>&</sup>lt;sup>72</sup> Food and Waterborne Disease Outbreak Data Search, FLA. HEALTH,

http://www.floridahealth.gov/diseases-and-conditions/food-and-waterborne-disease/food-waterborne-outbreak-data-

search.html?appSession=904352671017896&RecordID=&PageID=2&PrevPageID=1&cpipage=4 &CPISortType=&CPIorderBy= (last visited Apr. 17, 2015).

One such case, reported in 2009, began with a couple celebrating their pending nuptials and ended with a double amputation of the victim's legs.<sup>73</sup> Darrell Dishon, a diabetic, and his bride-to-be were vacationing in Panama City when he decided to try a raw oyster.<sup>74</sup> Within a day of the consumption, Mr. Dishon became violently ill and was taken to the hospital where his diagnosis was confirmed as Vibriosis and, likely because of his immunocompromised susceptibility, he developed septicemia.<sup>75</sup> Mr. Dishon slipped into a coma and woke up two weeks later with both of his legs amputated, an effort made by his treating physicians to halt the spread of the infection.<sup>76</sup> Mr. Dishon's recovery seemed to be going well, as he was transferred to a hospital in his home state of Ohio and ultimately released on orders of physical therapy, until his legs became infected again and his kidneys and liver began to fail.<sup>77</sup> In December of 2009, six months after eating those fateful raw oysters, Mr. Dishon lost his battle to Vibrio vulnificus.78

A survey, conducted in 2004, estimated that roughly twenty-seven percent of households in Florida eat raw ovsters, and approximately fifteen percent of those surveyed would qualify as being at a higher risk for contracting shellfishrelated illnesses.<sup>79</sup> Nearly fifty percent of those surveyed expressed no concern at all over the risks presented by consuming raw oysters.<sup>80</sup> An overwhelming ninety-

<sup>&</sup>lt;sup>73</sup> Lyndsey Layton, Industry, FDA at Odds on Raw Oysters, WASH. POST (Nov. 10, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/11/09/AR2009110903339.html.

<sup>&</sup>lt;sup>74</sup> Joe Satran, Vibriosis, Deadly Disease Associated with Raw Oysters, May Get More Common as Ocean Warms, HUFFINGTON POST (Feb. 7, 2013),

http://www.huffingtonpost.com/2013/02/07/vibriosis-oysters n 2617262.html (reporting that while Mr. Dishon's bride-to-be consumed ten raw oysters, he only ate two).

<sup>&</sup>lt;sup>75</sup> Id. See also Gardiner Harris, Food Agency Delays Ban on Ovsters After Outcry, N.Y. TIMES (Nov. 10, 2009), http://www.nytimes.com/2009/11/14/health/policy/14oyster.html? r=0 (noting that Mr. Dishon was hospitalized on the day of his planned wedding).

<sup>&</sup>lt;sup>76</sup> Layton, *supra* note 73 (reporting Mr. Dishon as stating; "You sit down for dinner with your family, and the next thing you know you're in a wheelchair for the rest of your life. Or worse."). <sup>77</sup> Satran, *supra* note 74 ("Facing a lifetime of dialysis, he . . . decided not to pursue further treatment.").

 $<sup>^{78}</sup>$  Id.

<sup>&</sup>lt;sup>79</sup> INTERSTATE SHELLFISH SANITATION CONF., RAW OYSTER CONSUMER FOLLOW-UP SURVEY: 2004 TECHNICAL REPORT 18 (2004), available at

http://www.issc.org/client resources/publications/2004%20raw%20oyster%20consumer%20surve y.pdf. <sup>80</sup> *Id.* at 69.

five percent of those responding to the survey denied taking any extra steps to avoid bacteria and other risks associated with eating raw oysters, like avoiding consumption of the raw shellfish in warmer summer months.<sup>81</sup> Considering these statistics together, the individuals that are significantly more susceptible to contracting Vibrio vulnificus in Florida fail to take any extra precautions to preserve their health when they decide to consume raw oysters. This data is troubling when Florida's approach to remedying the risk of Vibrio vulnificus in raw oysters revolves around spreading awareness of the risks through educational endeavors, thus placing the weight of preventing illness on the shoulders of the consumer.

#### C. The Problem with Public Notification of Vibrio Vulnificus

There is no easy method to address the threat of Vibrio vulnificus from Florida's coasts, as it is a natural presence in the state's coastal waters.<sup>82</sup> While the state cannot hope to expel the bacteria from its waters, it can protect the public from possible infection by warning residents and tourists of the risks posed by Vibrio vulnificus from all possible avenues of contracting the possibly life-threatening bacteria. Unfortunately, for recreational risks of Vibrio vulnificus, the warning often comes after infections have already been reported.<sup>83</sup> Moreover, raw oyster consumers receive general risk warnings of illness associated with shellfish, but such warnings only appear in restaurants that serve raw shellfish.<sup>84</sup>

<sup>&</sup>lt;sup>81</sup> Id. at 84.

<sup>&</sup>lt;sup>82</sup> Information on Vibrio Vulnificus, supra note 24.

<sup>&</sup>lt;sup>83</sup> Jaime Martinez-Urtaza et al., Climate Anomalies and the Increasing Risk of Vibrio

*Parahaemolyticus and Vibrio Vulnificus Illnesses*, 43 CLIMATE CHANGE & FOOD SCI., no. 7, Aug. 2010, at 1780, 1788, *available at* 

http://www.sciencedirect.com/science/article/pii/S0963996910000980 (noting that public health would be better served by a proactive testing protocol, rather than relying on studies conducted after illness outbreaks).

<sup>&</sup>lt;sup>84</sup> Division of Hotels and Restaurants Public Food Service Signs and Charts, FLA. DEP'T OF BUS. & PROF. REG., http://www.myfloridalicense.com/dbpr/HR/forms/sign\_and\_charts.html#oysters (last updated Nov. 15, 2013).

### 1. No Warning for Beachgoers

The stories of wound infections from Vibrio vulnificus all vary to some degree, but one common thread these incidents share is the total lack of warning or knowledge the individuals who contracted the bacteria had about the bacteria's presence in the waters they enjoyed before they fell ill.<sup>85</sup> One reported victim of Vibrio vulnificus was aware of the bacteria before she fell ill, but only after the media began to report other cases of infection occurring along Florida's coasts.<sup>86</sup> Kelly Johnson, a St. Augustine resident, had opted out of her daily swim for a week after hearing about a Vibrio outbreak on the news, but when she did return to the water, a small sore in her ear became infected with the bacteria.<sup>87</sup> In an attempt to get the word out, many more victims and their relatives are speaking out about their respective experiences with Vibrio vulnificus,<sup>88</sup> some arguing that they hope that by telling others of the risk, they or their loved ones will not have suffered in vain.<sup>89</sup>

There is no true warning system before an outbreak of Vibrio vulnificus because it is not one of the items for which the state's health department tests.<sup>90</sup> Juan A. Suarez, from the Florida Department of Health, was interviewed about the lack of warning given to beachgoers regarding the risk of wading in the waters

<sup>&</sup>lt;sup>85</sup> See, e.g., Deadly Bacteria, supra note 25 (quoting the wife of a Vibrio victim as having no knowledge of the bacteria before her husband was infected, although she and her husband had grown up in Florida and spent much of their lives in its coastal waters); Genuardi, *supra* note 47 (reporting that the son of a Vibrio victim had grown up in Miami and never heard of the bacteria); Skrzypek, *supra* note 32 (revealing that an interviewed beachgoer had little knowledge about Vibrio bacteria).

<sup>&</sup>lt;sup>86</sup> Pat Fallon, *Vibrio Vulnificus: The Deadly Bacteria in Florida Waters*, FLAGLER C. GARGOYLE (Nov. 7, 2013), http://gargoyle.flagler.edu/2013/11/vibrio-vulnificus-the-deadly-bacteria-in-florida-waters/.

<sup>&</sup>lt;sup>87</sup> *Id.* (noting that Ms. Johnson was unaware that Vibrio vulnificus was a recurring problem along Florida's coasts).

<sup>&</sup>lt;sup>88</sup> Tamara Lush, *10 in Florida Die from Bacteria Found in Saltwater*, SEATTLE TIMES (Oct. 11, 2013), http://seattletimes.com/html/health/2022022747\_killerseawaterxml.html (repeating Diane Holm, spokeswoman for the Lee County Health Department, who differentiated the cases in 2013 from other years based on the fact that more individuals were speaking to the media about their experiences with Vibrio).

<sup>&</sup>lt;sup>89</sup> Genuardi, *supra* note 47 (quoting the son of a Vibrio victim: "I hope my mom didn't die in vain.").

<sup>&</sup>lt;sup>90</sup> Id.

with Vibrio vulnificus: "We don't want to scare people away who have no risk . . . it doesn't affect everyone. Most healthy people will not respond to the organism. They are probably not at risk."<sup>91</sup> While there is some debate over whether Vibrio vulnificus infections are "rare"<sup>92</sup> or just "uncommon,"<sup>93</sup> what is not arguable is that the rate of infection is increasing, and as the oceans warm, the Vibrio population will grow and spread and, arguably, so will the risk of infection.<sup>94</sup> In this thread, support exists for the proposition, known as the precautionary principle, that scientific uncertainty should not be used as grounds to postpone preventative measures when there exists "serious or irreversible threats to the health of humans or ecosystems."<sup>95</sup> Thus, though illness resulting from Vibrio vulnificus may be rare, the danger it presents to the life and limb of Florida's public suggests that rarity is not a grounds to refuse preventative measures, like mandated notification.

### 2. Mandated Education Programs and Consumer Advisories

The risk of Vibrio vulnificus associated with eating raw oysters is more widely known than the risk of wound infections, as education measures regarding the risks of oysters are mandated in states that report two or more cases of related Vibrio vulnificus infection.<sup>96</sup> The state of Florida also requires a consumer

<sup>&</sup>lt;sup>91</sup> *Id.* (quoting Mr. Suarez, who works for the Florida Department of Health as an environmental epidemiologist).

<sup>&</sup>lt;sup>92</sup> Information on Vibrio Vulnificus, supra note 24.

<sup>&</sup>lt;sup>93</sup> Fallon, *supra* note 86 ("Professionals say it is uncommon to contract the bacteria, but that people with weak immune systems and preexisting health conditions are much more at risk to the bacteria entering the blood stream and contracting the bug and its side effects.").

<sup>&</sup>lt;sup>94</sup> L. Vezzulli et al., Long-Term Effects of Ocean Warming on the Prokaryotic Community: Evidence from the Vibrios, ISME J., 2012, at 21, 22, available at

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246245/pdf/ismej201189a.pdf ("There is substantial evidence that Vibrio-associated diseases are increasing worldwide with climate warming.").

<sup>&</sup>lt;sup>95</sup> Marco Martuzzi & Joel Tickner, *Introduction* to WORLD HEALTH ORGANIZATION, THE PRECAUTIONARY PRINCIPAL: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN 7, 7-8 (Marco Martuzzi & Joel Tickner eds., 2004) ("The principal originated as a tool to bridge uncertain scientific information and a political responsibility to act to prevent damage to human health and to ecosystems.").

<sup>&</sup>lt;sup>96</sup> Jennifer Flattery & Michelle Bashin, *A Baseline Survey of Raw Oyster Consumers in Four States*, ISSC VIBRIO VULNIFICUS EDUCATION ON POINT 1 (2004), *available at* http://www.issc.org/client\_resources/education/BaselineSurvey.pdf.

warning to be posted in establishments that serve raw oysters in an attempt to educate consumers about the possible risk.<sup>97</sup> Despite these measures, a survey conducted in 2004 recorded that thirty-eight percent of survey participants in Florida were unaware of any risk at all associated with eating raw oysters; of the individuals aware of a risk, only twenty-six percent were aware of all three survey groups that face a higher risk of infection.<sup>98</sup> About half of the individuals aware of the risk were so educated by either posted notices or via the television after news of infection outbreaks spread to the media.<sup>99</sup>

More startling is that less than thirty percent of individuals are told by their doctors that their health condition makes eating raw oysters a risky undertaking for them.<sup>100</sup> Fifty-seven-year-old Vincent Rhodes was in the beginning stage of his battle with cirrhosis of the liver when he visited Florida in July of 2012.<sup>101</sup> His doctor had not warned him of the risk raw oysters presented to him because of his condition, and while in Tampa, Mr. Rhodes decided to consume a dozen oysters with his wife at a beachside restaurant.<sup>102</sup> Within hours, Mr. Rhodes fell violently ill and had to be taken to the hospital where he remained in the Intensive Care Unit for several days, fighting off the Vibrio-induced illness.<sup>103</sup> While raw oyster risks are more widely known than that of wound infections, cases like Mr. Rhodes' continue to occur, and such agonizing<sup>104</sup> battles are largely avoidable with proper education for those at risk and streamlining the notification processes already in place. "Increasing consumer awareness is an important first step" toward addressing this problem and protecting the health of

<sup>&</sup>lt;sup>97</sup> Division of Hotels, supra note 84.

<sup>&</sup>lt;sup>98</sup> Flattery & Bashin, *supra* note 96, at 9 (counting as at-risk groups those suffering from liver disease, diabetes, or any other disease that would render the individual immunocompromised). <sup>99</sup> Id. at 11.

<sup>&</sup>lt;sup>100</sup> *Id.* 

<sup>&</sup>lt;sup>101</sup> Satran, *supra* note 74 (reporting that Mr. Rhodes was largely asymptomatic at the time of his visit). 102 Id.

<sup>&</sup>lt;sup>103</sup> Id. (describing Mr. Rhodes as being "completely gray" after contracting the bacteria, his developing a hernia from such violent vomiting, and the rapid progression of his underlying illness from tangling with Vibrio, pushing him into the need for a liver transplant).

<sup>&</sup>lt;sup>104</sup> *Id.* ("I'd rather have 20 more liver transplants than have vibrio again -- that's how bad I felt," Rhodes told The Huffington Post.").

these individuals from the risk presented by Vibriosis when consuming raw oysters.<sup>105</sup>

## III. EXISTING LEGAL PROTECTIONS FOR PUBLIC HEALTH – WATER QUALITY STANDARDS AND GULF SHELLFISH REGULATION

While it is true that Vibrio vulnificus is an omnipresent, natural flora dotting the Florida coasts, protections may exist within the current legal framework to better prepare the public for the risks associated with their favorite beach activities or raw shellfish hors d'oeuvres. Vibrio vulnificus is not the subject of many enacted laws or regulations, but it is possible to monitor the bacteria and risks to the public through various existing state and federal laws.

One of the Environmental Protection Agency's (EPA) duties is the protection of beaches and public health thereon. It promulgates and enforces water quality regulations.<sup>106</sup> Additionally, the Interstate Shellfish Sanitation Conference (ISSC) was formed to promote cooperation between the federal and state governments in making shellfish safer for public consumption,<sup>107</sup> which it accomplishes by working with the FDA to manage the National Shellfish Sanitation Program (NSSP).<sup>108</sup> The state of Florida has implemented the EPA's requisite water quality laws as federally mandated, enforced its own separate sampling policies to preserve water quality, and enacted certain guidelines from

<sup>&</sup>lt;sup>105</sup> Flattery & Bashin, *supra* note 96, at 4 (noting that awareness in Florida is higher than in most states, but the behaviors associated with that knowledge are ineffective to prevent contracting the bacteria—like avoiding shellfish in the summer months or only getting oysters from trusted venues).

 <sup>&</sup>lt;sup>106</sup> LEARN: EPA's Role in Protecting Beaches, U.S. ENVTL. PROTECTION AGENCY, http://www2.epa.gov/beaches/learn-epas-role-protecting-beaches (last updated July 30, 2014)
 ("Following the BEACH Act of 2000, EPA expanded the focus of its efforts to improve the quality of coastal recreation waters and protect the health of beach goers.").
 <sup>107</sup> INTERSTATE SHELLFISH SANITATION CONF., http://www.issc.org/ (last visited Apr. 17, 2015)

<sup>&</sup>lt;sup>10</sup> INTERSTATE SHELLFISH SANITATION CONF., http://www.issc.org/ (last visited Apr. 17, 2015) ("The Interstate Shellfish Sanitation Conference (ISSC) was formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community.").

<sup>&</sup>lt;sup>108</sup> National Shellfish Sanitation Program (NSSP), U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm (last updated Sep. 30, 2014) ("The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs.").

the NSSP to protect the sanitation of shellfish. Many laws could be used in the effort to promote awareness of the bacteria, either as written or with minor modifications to shape the law as one that meets the demands of Vibrio risks. This patchwork of laws and regulations has proven ill-equipped to prevent or even decrease public exposure to Vibrio vulnificus.

### A. The BEACH Act and Florida's Health-Based Bacteria Standards

Several existing federal and state laws regulate and protect the water quality of recreational waters. The Clean Water Act (CWA) was enacted to achieve, among other goals, "wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water."<sup>109</sup> Congress amended the Clean Water Act with the Beaches Environmental Assessment and Coastal Health Act (BEACH Act) of 2000, which requires states with coastal waters used for recreation to adopt bacteria-based water quality standards to better protect human health.<sup>110</sup> This Act could potentially apply to the hazards that Vibrio vulnificus presents to public health.

The BEACH Act amendments require states to submit and enforce water quality standards for certain pathogens<sup>111</sup> as applicable to their coastal recreational waters, as well as monitor those pathogens' effects on indigenous shellfish population.<sup>112</sup> In developing these water quality criteria, the BEACH Act mandates that states conduct studies to assess the "potential human health risks resulting from exposure to pathogens in coastal recreation waters" and appropriate

<sup>&</sup>lt;sup>109</sup> Clean Water Act, 33 U.S.C. § 1251(a)(2).

<sup>&</sup>lt;sup>110</sup> Beaches Environmental Assessment and Coastal Health Act of 2000, Pub. L. No. 106-284, 114 Stat. 870-77 (2000). *See also EPA Proposes More Protective Water Quality Standards for Bacteria*, U.S. ENVTL. PROTECTION AGENCY (July 2004),

http://water.epa.gov/lawsregs/lawsguidance/beachrules/bacteria-rule-fs.cfm.

<sup>&</sup>lt;sup>111</sup> The Clean Water Act, as amended by the BEACH Act in 2000, requires each state to develop testing measures and report on certain pathogens found in surface waters and how they influence "plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation," as well as "the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and on the effects of pollutants on biological community diversity, productivity, and stability." 33 U.S.C. § 1314(a)(1).

<sup>&</sup>lt;sup>112</sup> *Id.* § 1314(a)(5)(B) (explaining the purpose of the water quality requirement as protecting public health and indigenous marine populations from possible pollutants).

indicators for detecting such harmful pathogens.<sup>113</sup> Seeking to protect the health and safety of individuals in their pursuit of recreation along the coasts, as well as the integrity of coastal shellfish, the BEACH Act provides a valuable foundation for monitoring the presence and effect of Vibrio vulnificus along the coasts. However, because the BEACH Act's aim is monitoring pathogenic bacteria introduced to recreational waters via fecal contamination, the naturally-occurring vibrio bacteria have not made the list.<sup>114</sup>

One of the most important aspects of the BEACH Act is its requirement that all states develop their own bacteria standards as part of their water quality criteria, or adopt the standards promulgated by the EPA.<sup>115</sup> Under the BEACH Act, states are given the responsibility of writing the standards for pathogens in recreational waters through three options: the states can adopt the criteria set forth by the EPA, modify the EPA's criteria to reflect the state's specific conditions, or adopt its own criteria that is "as protective as" EPA recommendations "based on scientifically-defensible methods."<sup>116</sup> States have the option to develop more stringent water quality standards than EPA requires.<sup>117</sup>

Seeking only to make its water quality criteria "as protective as" that of the EPA, Florida codified its surface bacteria water quality criteria,<sup>118</sup> testing for fecal coliform bacteria based on an earlier standard set by the EPA.<sup>119</sup> Fecal coliform bacteria are widespread bacteria found in human feces, as well as in animal waste and soil, and were used as indicator bacteria by the EPA for the likelihood of other disease-causing bacteria; the presence of these bacteria

<sup>&</sup>lt;sup>113</sup> *Id.* § 1254(v)(1)-(2).

<sup>&</sup>lt;sup>114</sup> U.S. ENVTL. PROTECTION AGENCY, NATIONAL BEACH GUIDANCE AND REQUIRED PERFORMANCE CRITERIA FOR GRANTS, 2014 EDITION 7 (2014).

<sup>&</sup>lt;sup>115</sup> 2004 Bacteria Rule for Coastal and Great Lakes Recreation Waters, U.S. ENVTL. PROTECTION AGENCY, http://water.epa.gov/lawsregs/lawsguidance/beachrules/bacteria-rule.cfm (last updated Aug. 8, 2013) ("Although states are required to write the standards, [the EPA has] to approve them.").

<sup>&</sup>lt;sup>116</sup> Id.

 $<sup>^{117}</sup>_{118}$  40 C.F.R. § 131.4(a).

<sup>&</sup>lt;sup>118</sup> See generally FLA. ADMIN. CODE ANN. § 62-302.530 (listing, in table form, the specific items that are monitored in surface waters by the state of Florida, including arsenic, biological integrity, and nitrate).

<sup>&</sup>lt;sup>119</sup> 5.11 Fecal Bacteria, U.S. ENVTL. PROTECTION AGENCY,

http://water.epa.gov/type/rsl/monitoring/vms511.cfm (last updated Mar. 6, 2012).

indicate that swimming in these regions or consuming shellfish harvested therefrom may not be safe.<sup>120</sup> As of 1986, the EPA no longer recommends using this bacteria as an indicator, however, and has since recommended switching to the use of E. coli and enterococci bacteria to test waters for the presence of dangerous pathogens, specifying enterococci as the best choice for saltwater regions.<sup>121</sup>

The Florida Healthy Beaches Program, administered by the Florida Department of Health and funded by a grant from the EPA, tests waters using both the previously recommended fecal coliform and current indicator enterococci bacteria, although the state's code has yet to reflect a legal requirement to use the better indicator.<sup>122</sup> This program tests designated areas weekly, and regions with elevated levels of enterococci are given a "poor" rating coupled with an advisory being issued for the site.<sup>123</sup> The problem with using any of these bacteria to determine the presence of pathogens in selected waters is that the tests used are unable to distinguish between enteric (fecal) bacteria and environmental bacteria, like Vibrio, in the sampled waters.<sup>124</sup>

The CWA requires all states to submit to the EPA "biennial water quality reports," known as 305(b) reports, to describe the extent to which the state's waters are achieving their designated uses.<sup>125</sup> Waters that are not meeting their

<sup>&</sup>lt;sup>120</sup> Id.

<sup>&</sup>lt;sup>121</sup> U.S. ENVTL. PROTECTION AGENCY, AMBIENT WATER QUALTY CRITERIA FOR BACTERIA – 1986 5-6 (1986).

<sup>&</sup>lt;sup>122</sup> Florida Healthy Beaches Program, FLA. HEALTH,

http://www.floridahealth.gov/environmental-health/beach-water-quality/index.html (last visited Apr. 17, 2015) (describing the founding of the program as a pilot program in 1998 in five counties of Florida on a grant from the EPA, which was extended to all of the state's thirty-four coastal counties in 2000).

<sup>&</sup>lt;sup>123</sup> *Id.* ("If an enterococci result were observed to exceed 104 colony forming units per 100 milliliters of beach water sampled and a resampling result also exceeds this value, then an 'Advisory' would be issued for the sampling site.").

<sup>&</sup>lt;sup>124</sup> FLA. DEP'T OF ENVTL. PROTECTION, DIV. OF ENVTL. ASSESSMENT AND RESTORATION, BACTERIA CRITERIA TECHNICAL ADVISORY COMMITTEE MEETING 13 (Aug. 20, 2013), *available at* 

http://www.dep.state.fl.us/water/wqssp/docs/bacteria/0813tac/bacteria\_criteria\_background\_whiti ng.pdf.

<sup>&</sup>lt;sup>125</sup> Division of Envtl. Assessment and Restoration, Fla. Dep't of Envtl. Protection, Integrated Water Quality Assessment for Florida: 2014 Sections 303(d), 305(b), and

designated purposes are considered "impaired."<sup>126</sup> Under the current sampling and testing procedures that use only fecal bacteria as indicators, only about four percent of beach locations in Florida return impaired results, meaning that either recreational use or shellfish harvesting would not be safe as a designated use for the region.<sup>127</sup> The Florida Department of Health does not currently test for Vibrio vulnificus as part of the Florida Healthy Beaches Program because the bacteria is natural to the marine environment,<sup>128</sup> and the bacteria is not regulated via the water quality criteria for the state.<sup>129</sup> However, Vibrio vulnificus often causes the same type of harm as the pathogens<sup>130</sup> for which the Program currently tests to preserve human health and public safety in shellfish consumption and coastal recreational activities. The failure to test for Vibrio vulnificus may cause these numbers to be unrepresentative of the risk associated with these activities.

Vibrio vulnificus could be added to the list of water quality standards in Florida by the Water Quality Standards Program (WQSP), administered by the Florida Department of Environmental Protection.<sup>131</sup> The WQSP reviews, establishes, and revises the state's water quality standards.<sup>132</sup> These tasks are

<sup>128</sup> Our Gulf Environment, FLA. DEP'T OF HEALTH IN SARASOTA COUNTY,

<sup>131</sup> Water Quality Standards Program, FLA. DEP'T OF ENVTL. PROTECTION, http://www.dep.state.fl.us/water/sas/ (last updated Aug. 25, 2015).

 $^{132}$ *Id.* 

<sup>314</sup> REPORT AND LISTING UPDATE 1 (Apr. 2014), available at

http://www.dep.state.fl.us/water/docs/2014\_integrated\_report.pdf (referring to designated uses as anything from recreation to shellfish harvesting).

<sup>&</sup>lt;sup>126</sup> *Id.* at 3 (noting that only sampled waters listed as a category five are considered to be impaired, meaning that the sample shows that "at least one designated use is not being supported or is threatened").

<sup>&</sup>lt;sup>127</sup> *Id.* at 25 ("[P]rimary contact and recreation use support and shellfish harvesting use support are sometimes limited by the presence of bacteria in the water column . . .."). *Contra Testing the Waters 2014*, NATURAL RES. DEFENSE COUNCIL, http://www.nrdc.org/water/oceans/ttw/fl.asp (last updated June 2, 2014) (using a more stringent enterococci level notification requirement recommended by the EPA, this study reflected that ten percent of Florida beaches would be considered impaired due to bacteria levels).

https://ourgulfenvironment.scgov.net/Pages/Bacteria.aspx (last visited Apr. 17, 2015). <sup>129</sup> As noted by the absence of Vibrio vulnificus on the table delineating water quality criteria for Florida. FLA. ADMIN. CODE ANN. § 62-302.530.

<sup>&</sup>lt;sup>130</sup> Our Gulf Environment, supra note 128 ("When . . . enteric bacteria are detected in high concentrations in recreational waters, there is a risk of illness and infections. Some people who swallow water while swimming or have contact with water entering the skin through a cut or sore may become ill with gastrointestinal illnesses, infections or rashes.").

carried out by the Standards Development Section (SDS) of the WQSP, which conducts triennial reviews of Florida's surface water quality standards and proposes revisions to these rules.<sup>133</sup> The SDS considers the economic impact of a revision to the water quality standards, gives public workshops on the proposed revision, and allows a period for public comment on the potential revision.<sup>134</sup> The revisions, once adopted and certified by the state, must then be approved by the EPA.<sup>135</sup> Florida could utilize this process, coupled with its ability to enact more stringent water quality standards, to regulate environmental bacteria like Vibrio vulnificus.

# B. Federal and State Regulations on the Harvesting of Gulf Coast Oysters and Vibrio Vulnificus

Shellfish are invaluable to the economy of Florida, bringing in over \$20 million annually and employing over 2,500 people.<sup>136</sup> Reflecting this value are the extensive laws, regulations, and agencies in place to monitor the harvesting and processing of shellfish items, including oysters. The NSSP is the primary source of guidelines for state regulation of shellfish procedures, and it establishes the minimum necessary requirements for such regulation, as well as the protection of the public health of consumers.<sup>137</sup> The Program's guidelines for harvesting procedures, outbreaks of shellfish-related illnesses, and the Vibrio Vulnificus

<sup>&</sup>lt;sup>133</sup> Surface Water Quality Standards, FLA. DEP'T OF ENVTL. PROTECTION,

http://www.dep.state.fl.us/water/wqssp/index.htm (last updated July 2, 2015). Triennial reviews are required by federal law. 40 C.F.R. § 131.20(a).

 <sup>&</sup>lt;sup>134</sup> FLORIDA DEPARTMENT OF ENVIRONMENTAL PROTECTION, PUBLIC WORKSHOPS FOR FLORIDA'S TRIENNIAL REVIEW OF WATER QUALITY STANDARDS 4-8 (Sept. 2015). Public participation in water quality revisions is required by the EPA under federal law. *See* 40 C.F.R. § 131.20(b).
 <sup>135</sup> 40 C.F.R. § 131.20(c).

<sup>&</sup>lt;sup>136</sup> Shellfish: A Valuable and Renewable Natural Resource, FLA. DEP'T OF AGRIC. & CONSUMER SERVICES, http://www.freshfromflorida.com/Divisions-Offices/Aquaculture/Agriculture-Industry/Shellfish (last visited Apr. 17, 2015) (classifying as shellfish only oysters, mussels, and clams).

<sup>&</sup>lt;sup>137</sup> NAT'L SHELLFISH SANITATION PROGRAM, GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH 2013 REVISION 10-11 (2013), *available at* 

http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM41552 2.pdf ("Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, EPA, NOAA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP.").

Control Plan are all important for the Florida Gulf coast's oysters.<sup>138</sup> Some portions of the NSSP guidelines are mandatory for states, even if the state does not formally adopt all provisions in its regulation of shellfish.<sup>139</sup>

The NSSP guidelines require that surveys are taken of the water quality in oyster-growing areas prior to the harvesting of any oysters for human consumption. The survey is then used to classify the growing area as approved or restricted.<sup>140</sup> In Florida, the Shellfish Harvesting Program, administered by the Florida Department of Agriculture and Consumer Services,<sup>141</sup> is responsible for undertaking this process<sup>142</sup> and subsequently giving growing areas status classifications—either open, closed, or inactive for purposes of harvesting—based on the presence of bacteria or pathogens in the waters.<sup>143</sup> All states are required to ensure that oysters and other shellfish are only harvested from those areas classified as open, or with approval in areas classified as prohibited, restricted, or conditionally restricted.<sup>144</sup> The NSSP guidelines require states to monitor and enforce approved harvesting practices by patrolling growing areas, licensing shellfish harvesters, identifying areas where harvesting is not permitted, and assessing penalties against those who do not comply with harvesting regulations.<sup>145</sup>

<sup>&</sup>lt;sup>138</sup> See generally id.

 $<sup>^{139}</sup>$  Id. at 39 (including the sanitary standards for shellfish growing areas as a mandatory provision for compliance).

<sup>&</sup>lt;sup>140</sup> *Id.* (noting that growing areas can receive one of the following statuses based on the sanitation survey, "approved, conditionally approved, restricted or conditionally restricted," based on levels of fecal coliform bacteria).

<sup>&</sup>lt;sup>141</sup> Division of Aquaculture, FLA. DEP'T OF AGRIC. & CONSUMER SERVICES,

http://www.freshfromflorida.com/Divisions-Offices/Aquaculture (last visited Jan. 24, 2016). <sup>142</sup> FLA. DEP'T OF ENVTL. PROTECTION, *supra* note 124, at 7.

<sup>&</sup>lt;sup>143</sup> Open status growing areas may be harvested subject to the approved, conditionally approved, or conditionally restricted classification that it may be assigned. Closed status growing areas may obtain this designation temporarily due to emergency circumstances, the presence of pathogens that are dangerous to the public health, or failure to conduct a survey. Inactive growing areas are those where harvesting no longer occurs, and these areas will be closed. NAT'L SHELLFISH SANITATION PROGRAM, *supra* note 137, at 45.

<sup>&</sup>lt;sup>144</sup> *Id.* at 66-71.

<sup>&</sup>lt;sup>145</sup> *Id.* (noting that licensing of shellfish harvesters is required only for those involved in commercial harvest and requires that "the harvester [] sell only to dealers listed on the Interstate Certified Shellfish Shippers List," and that the state is required to "chart, describe, and mark the boundaries of growing areas classified as restricted, conditionally restricted, or prohibited, or in a closed status," with fixed objects, landmarks, or easily recognizable descriptions).

As a member of the ISSC, Florida implements the NSSP-required classification and management regulations via the Shellfish Environmental Assessment Section (SEAS) of the Department of Agriculture and Consumer Services, which samples coastal waters using fecal coliform bacteria as indicator pathogens for those that would be considered dangerous to human health.<sup>146</sup> The state codified the NSSP's regulations for oyster harvesting areas in its Administrative Code in 2006, delineating the approved methods for classifying these areas.<sup>147</sup> Florida law requires, as of July 2015, that those commercially harvesting oysters have a special designation on their valid saltwater products license, which shall be earned after completing an approved shellfish harvesting course.<sup>148</sup>

The NSSP guidelines extend beyond regulating oyster harvesting and set standards for shellfish-related illness outbreaks.<sup>149</sup> The Program's guidelines require any state in which two or more individuals contract an oyster-implicated illness to review the stricken individual's food history, handling practices, and symptoms to determine if the illness was, in fact, caused by shellfish.<sup>150</sup> If the illness was caused by consuming oysters, and it is clear that the contamination of the oyster occurred before it was harvested, the state must declare the harvesting area closed, notify any receiving states, the ISSC, and the FDA that there is a health risk with oysters cultivated from that region, and initiate recall procedures, including all products possibly contaminated before harvesting.<sup>151</sup> If the oyster contamination was the result of a naturally occurring pathogen, the area will remain closed until it is ascertained that the pathogen is not a public health

 <sup>&</sup>lt;sup>146</sup> Shellfish, supra note 136 (describing SEAS, a division of the Bureau of Aquaculture Environmental Services, as being located in Tallahassee and responsible for "the 1,200 bacteriological sampling stations in 39 shellfish harvesting areas, encompassing 1,430,854 acres").
 <sup>147</sup> FLA. ADMIN. CODE ANN. § 5L-1.003.

<sup>&</sup>lt;sup>148</sup> *Id.* § 68B-27.018 (excepting from the special designation requirement for harvesting those that have a valid Apalachicola Bay oyster harvesting license as well as a valid saltwater products license).

<sup>&</sup>lt;sup>149</sup> NAT'L SHELLFISH SANITATION PROGRAM, *supra* note 137, at 23 (noting once more that states must comply with this provision regardless of whether it has been codified by the state). <sup>150</sup> *Id*.

<sup>&</sup>lt;sup>151</sup> *Id.* (requiring the harvesting area be closed only if the contamination of the oyster occurred prior to harvesting; post-harvesting contamination only requires the notification stated above and a possible voluntary recall).

concern.<sup>152</sup> The NSSP guidelines specifically regulate Vibrio illnesses as they relate to shellfish production, requiring states to record annually the number of Vibrio illnesses relating to shellfish consumption.<sup>153</sup>

The NSSP mandated a Vibrio vulnificus Control Plan in 2012 for those states reporting two or more septicemia illnesses reportedly linked to the bacteria via consumption of raw or undercooked shellfish.<sup>154</sup> The Control Plan requires these states to evaluate the risk of the bacteria annually to consider the seasonality of outbreaks, number of illness cases associated with the consumption of commercially harvested shellfish, and levels of the bacteria growing in the water.<sup>155</sup> The Plan further requires the state to identify triggers affecting risks of the bacteria<sup>156</sup> and implement control measures to reduce the risk of illnesses.<sup>157</sup> Florida implements the required Vibrio vulnificus Control Plan by requiring the shellfish industry to follow a "rigid time-temperature matrix" involving timely deliveries and refrigeration of raw oysters.<sup>158</sup> Florida also regulates the seasons in which oysters may be harvested on a regional basis, putting a general moratorium on harvesting oysters from the first of July to the thirtieth of September each year,

<sup>&</sup>lt;sup>152</sup> *Id.* at 24.

<sup>&</sup>lt;sup>153</sup> *Id.* at 26 (applying to both Vibrio vulnificus and its less violent sibling, Vibrio parahaemolyticus).

<sup>&</sup>lt;sup>154</sup> *Id.* at 29.

<sup>&</sup>lt;sup>155</sup> NAT'L SHELLFISH SANITATION PROGRAM, *supra* note 137, at 29.

<sup>&</sup>lt;sup>156</sup> The state may choose one or more of the following triggers, as listed by the NSSP guideline: area water temperatures, air temperatures, salinity, harvesting techniques, or other factors that would indicate a risk. *Id*.

<sup>&</sup>lt;sup>157</sup> *Id.* at 29-31 (requiring a state to employ one or more of the following measures to reduce the risk of illness associated with Vibrio vulnificus: labeling oysters with a warning that shucking should be conducted by a certified dealer when the water temperature exceeds seventy degrees Fahrenheit; requiring all oysters intended for the raw market to undergo approved post-harvest processing when the water temperature exceeds seventy degrees Fahrenheit; reducing the time the oysters are exposed to open air; or alternative controls the state may deem fit).

<sup>&</sup>lt;sup>158</sup> Florida Department of Agriculture and Consumer Services, *Interstate Shellfish Sanitation Conference Yields Regulatory Changes*, 87 FLA. AQUACULTURE 1, 3 (Feb. 2014) (requiring refrigeration of the shellfish). From May to July, oysters must be delivered to dealers by 11:30 AM, and from August to October, by noon. Oysters must be kept between fifty-five degrees and sixty-five degrees Fahrenheit depending on the cooling system employed. *See generally* FLA. ADMIN. CODE ANN. 5L-1.008 (explaining the time-temperature matrix).

making an exception for Apalachicola Bay,<sup>159</sup> where certain regions are deemed open for harvesting throughout the year.<sup>160</sup>

In 2009, the FDA considered a ban on raw oysters from the Gulf Coast for eight months of every year, arguing this unilateral move as "necessary to protect public health" because Vibrio vulnificus sickens, on average, approximately thirty people each year.<sup>161</sup> Presumably because of the economic impacts this would have on the industry, the FDA has since postponed the measure.<sup>162</sup> This was a hotly contested proposal, with those involved in the shellfish industry and raw oyster lovers seeking to stop what they saw as a devastatingly restrictive measure.<sup>163</sup> On the other side of the battle are the family members, and in some cases, victims of Vibrio vulnificus illnesses associated with raw oyster consumption who see these recurring illnesses, and sometimes deaths, as entirely preventable.<sup>164</sup>

Despite efforts to refrigerate shellfish to avoid bacteria growth and close oyster growing areas during the hottest summer months—though these closures are limited and many exceptions apply—individuals are still contracting the bacteria through the consumption of raw or undercooked oysters from the Gulf Coast, and reported cases of Vibrio vulnificus appear to be increasing.<sup>165</sup> Education and notification, which currently are the consumer's responsibility,

<sup>&</sup>lt;sup>159</sup> Approximately ninety percent of Florida's oysters are produced in Apalachicola Bay. FLA. FISH & WILDLIFE CONSERVATION COMM'N, 2012-2013 FLA. GULF COAST OYSTER DISASTER REPORT (May 2013), *available at* 

http://www.sarasota.wateratlas.usf.edu/upload/documents/Florida\_oyster\_disaster\_report-2013.pdf.

<sup>&</sup>lt;sup>160</sup> FLA. ADMIN. CODE ANN. 68B-27.019.

<sup>&</sup>lt;sup>161</sup> Press Release, East Coast Shellfish Growers Association, U.S. FDA Ban on Raw Oysters Will Put Thousands of Gulf Coast Men and Women out of Work, and Threaten Other Regions (Oct. 22, 2009), *available at* 

http://www.ecsga.org/Pages/Issues/Human\_Health/FDA\_OysterBanPressRelease10-09.pdf. <sup>162</sup> *Id.* (arguing that the law would have perilous effects on the economy, given that the unemployment rate at the time was near ten percent).

<sup>&</sup>lt;sup>163</sup> Gardiner Harris, U.S. Plans Raw Warm-Water Oyster Ban, N.Y. TIMES (Nov. 11, 2009), http://www.nytimes.com/2009/11/12/health/policy/12oyster.html?partner=rss&emc=rss&\_r=0. <sup>164</sup> Id. (reporting the statements of the daughter of a Vibrio victim: "They know that in 2010, 15

people will die like my father did even though there's a surefire way to prevent that . . . [o]f course the F.D.A. should step in.").

<sup>&</sup>lt;sup>165</sup> Bross et al., *supra* note 39 ("*V. vulnificus* is one of the few foodborne illnesses with an increasing incidence.").

appear to be the best strategy to avoid contracting the bacteria and its subsequent illnesses. While these regulations are a step in the right direction, taking this foundation a step further, as seen in the third part of this article discussing the California regulations, could potentially avoid the preventable illnesses induced by the Vibrio bacteria.

## C. Notification Requirements for Vibrio Vulnificus in Florida

Keeping those at risk abreast of the presence of Vibrio vulnificus along their shores and in their food is an important step to reducing the reported cases of illness from the bacteria. A significant percentage of the population remains unaware of the risk posed by Vibrio vulnificus, or even the presence of the possibly lethal bacteria.<sup>166</sup> While consumers of raw oysters are provided some warning, beachgoers need to know where to look to find notification of bacteria in the waters they intend to enjoy.

## 1. Beach Warnings and Advisories

Because Florida does not test specifically for the presence of Vibrio vulnificus along its coasts, there is no advance warning or advisory system for this particular bacteria.<sup>167</sup> The public often receives notice of the bacteria after an outbreak of associated illness is reported, and the warnings are generally proliferated through the local media where the outbreak occurred.<sup>168</sup> Though public warnings for Vibrio are not required, both federal and state regulations do require notification of other bacteria lurking along the coast, and amending these to apply to Vibrio vulnificus could solve the problem of lack of notification. As a starting point, the BEACH Act provides for mandatory, "prompt notification of the public [and] local governments" of excess or likely excess of water quality

<sup>&</sup>lt;sup>166</sup> Enjoy the Water, supra note 28.

<sup>&</sup>lt;sup>167</sup> Florida Healthy Beaches Program, supra note 122.

<sup>&</sup>lt;sup>168</sup> See generally Skrzypek, supra note 32; Mary Beth Quirk, Gulf Coast Health Officials Warning Swimmers After Flesh-Eating Bacteria Kills 10, Hospitalizes 32, CONSUMERIST (July 30, 2014), http://consumerist.com/2014/07/30/gulf-coast-health-officials-warning-swimmers-after-flesh-eating-bacteria-kills-10-hospitalizes-32/; Flesh-Eating Bacteria Kills 10th Victim in Florida, SPACE COAST DAILY (July 30, 2014), http://spacecoastdaily.com/2014/07/flesh-eating-bacteria-kills-10th-victim-in-florida/.

standards in recreational waters.<sup>169</sup> The BEACH Act also requires those states that receive a federal grant under the Act to report data collected on water quality and measures taken to notify the public when water quality standards are not met.<sup>170</sup>

The Florida legislature has codified the authority of the Department of Health to issue public warnings or advisories regarding water quality, specifically when coastal or intracoastal waters exceed bacterial standards.<sup>171</sup> The law requires that when a public health advisory is issued warning against swimming in coastal waters due to elevated levels of bacteria, the issuing authority must also notify the local county or municipality, as well as the local Department of Environmental Protection, of the advisory.<sup>172</sup> The Florida Healthy Beaches Program (FHBP) was given authority, under the statute, to monitor coastal waters and issue advisories when the waters exceed given standards; the data and advisories are then posted to the Beach Advisory and Closing On-Line Notification (BEACON) system on the FHBP website.<sup>173</sup> When the FHBP samples coastal waters and enterococci bacteria are elevated, it issues an "advisory", and when fecal coliform levels are elevated, the Program issues a "warning."<sup>174</sup>

The issuing of public health advisories or warnings is conducted by county health departments, which then report these matters to local officials and the State Health office and may resample the monitored areas for the conditions requiring the advisories and/or warnings.<sup>175</sup> Public notification is conducted by the county health departments via three methods: notifying the media; posting sampling results and advisory data on the county FHBP website or the county's Department of Health website; and posting signs at the failing sample location on the beach

<sup>&</sup>lt;sup>169</sup> 33 U.S.C. § 1346(a)(1)(B).

<sup>&</sup>lt;sup>170</sup> *Id.* § 1346(b)(3)(A).

<sup>&</sup>lt;sup>171</sup> FLA. STAT. § 514.023(1)-(3) ("The department may adopt and enforce rules to protect the health, safety, and welfare of persons using the beach waters and public bathing places of the state.").

<sup>&</sup>lt;sup>172</sup> *Id.* § 514.023(4) (stating that the local Department of Environmental Protection is then required to investigate the occurrence and possible causes).

<sup>&</sup>lt;sup>173</sup> Bart Bibler, Chief, Bureau of Water Programs, Florida Health Beaches Program 2-7 (2005), *available at* http://coastalconference.org/h20\_2005/pdf/2005/2005\_10-26-

Wednesday/Session\_1B-Beach\_Water\_Quality/Bibler-Floridas\_Healthy\_Beaches\_Program.pdf. <sup>174</sup> *Id.* at 14.

 $<sup>^{175}</sup>$  Id. at 16 (basing type of public notification on type of bacteria).

and at points of public beach access nearby.<sup>176</sup> These are measures that could be easily adapted to warn the public of the risks of Vibrio vulnificus and help reduce the amount of Vibrio-related wound infections.

## 2. Raw Oyster Consumer Advisories

Due to the higher incidence and fatality rates of Vibrio vulnificus as contracted through raw oysters,<sup>177</sup> more direct means of public notification exist to warn would-be consumers and high-risk individuals of the dangers of eating raw shellfish. The NSSP guidelines require states to notify "receiving states, the ISSC and the FDA Regional Shellfish Specialist" of a potential health risk associated with oysters when there has been an illness outbreak of two or more individuals related to oyster consumption.<sup>178</sup> Should a recall of the oyster product be deemed necessary, the guidelines suggest the state "issue public warnings if necessary to protect public health."<sup>179</sup> Under the guidelines, the FDA also has the authority to determine that public warning is necessary, and if the state fails to implement effective warning measures, the FDA can issue public warnings "when appropriate."<sup>180</sup> The NSSP has stressed the importance of public warnings of shellfish-related illness as being foundational to protecting public consumers from shellfish that may be harboring bacteria.<sup>181</sup> The NSSP has required states with two or more reported cases of Vibrio vulnificus from oysters to implement a "Vibrio vulnificus Risk Management Plan," with consumer education being a primary, mandatory element of the state's plan.<sup>182</sup>

<sup>&</sup>lt;sup>176</sup> *Id.* at 17 (picturing the issued advisory, which reads: "ADVISORY: HIGH BACTERIAL LEVELS HEALTH RISK AT THIS TIME SWIMMING <u>NOT</u> RECOMMENDED").

<sup>&</sup>lt;sup>177</sup> Enjoy the Water, supra note 28 ("According to FDA, 90% of all Vibrio vulnificus illnesses (morbidities and mortalities) in the U.S. result from consumption of raw Gulf coast oysters."). <sup>178</sup> NAT'L SHELLFISH SANITATION PROGRAM, supra note 137, at 23.

<sup>&</sup>lt;sup>179</sup> *Id.* at 24.

<sup>&</sup>lt;sup>180</sup> *Id*.

<sup>&</sup>lt;sup>181</sup> *Id.* at 151 ("Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health.").

<sup>&</sup>lt;sup>182</sup> Flattery & Bashin, *supra* note 96, at 1 (reporting the main criteria for success for such state plans as the increase of consumer awareness by forty percent and the proportion of consumers who are at high-risk for illness who stop eating raw oysters by fifteen percent).

Florida's plan to reduce the risk of Vibrio vulnificus for raw oysters lists consumer education as its primary and most important tool in reducing shellfish illnesses.<sup>183</sup> Other than brochures and media exposure, one important way Florida has decided to educate and warn consumers of the risks of raw oysters is through outreach programs,<sup>184</sup> mainly educational workshops conducted by the state with the help and funding of the ISSC.<sup>185</sup> In the past, workshops were conducted by the state and the ISSC for food handlers and inspectors at the retail level.<sup>186</sup> as well as with healthcare providers, an important link in the education scheme for at-risk individuals, in order to better educate these officials on the risks and recommendations for dealing with Vibrio.<sup>187</sup> These presentations recommend that healthcare providers urge individuals considered at risk to avoid eating raw oysters, and if they are going to eat any shellfish, to make sure it is thoroughly cooked or to eat those items that have been treated post-harvest to reduce Vibrio risks.<sup>188</sup> The programs also endeavor to acquaint healthcare providers with the symptoms of Vibrio illnesses, as timely treatment is important to saving lives and limbs.<sup>189</sup> Florida also holds conferences to distribute Vibrio vulnificus informational items and provides pamphlets to liver disease support groups, a group that has a higher risk of contracting a Vibrio illness.<sup>190</sup>

The most beneficial aspect of consumer warning is the mandatory consumer advisories for Gulf shellfish. Florida has required any restaurant serving

<sup>&</sup>lt;sup>183</sup> William Huth et al., ISSC Vibrio Education Subcommittee, Oyster Demand Adjustments to Alternative Consumer Education and Post Harvest Processes in Response to Vibrio Vulnificus (May 5, 2009), *available at* http://www.issc.org/client\_resources/huth-martin%20issc%20presentation%205-5-2009.pdf.

<sup>&</sup>lt;sup>184</sup> See generally Roberta M. Hammond, Food and Waterborne Disease Coordinator, Bureau of Environmental Epidemiology, Vibrio Vulnificus: A Health Professional's Guide to Infection, Prevention, and Treatment (2005), *available at* 

http://fycs.ifas.ufl.edu/foodsafety/2005/adobe/vv%20health%20care%202004.pdf.

 $<sup>^{185}</sup>$  Interstate Shellfish Sanitation Conference, Cooperative Agreement # MX-

<sup>97417201-0 &</sup>quot;EDUCATING THE AT-RISK CONSUMER" 3 (2005), available at

http://www.issc.org/client\_resources/publications/educatingtheatriskconsumerfinalreport.pdf. <sup>186</sup>/<sub>167</sub> *Id.* at 4.

<sup>&</sup>lt;sup>187</sup> Hammond, *supra* note 184, at 28.

 $<sup>^{188}</sup>$  *Id.* at 39.

<sup>&</sup>lt;sup>189</sup> *Id.* at 18.

 $<sup>^{190}</sup>$  *Id.* at 40.

raw oysters to post or display on the menu, a visible placard, or other viable location, the following consumer advisory warning:

Consumer Information: There is risk associated with consuming raw oysters. If you have chronic illness of the liver, stomach or blood or have immune disorders, you are at greater risk of serious illness from raw oysters, and should eat oysters fully cooked. If unsure of your risk, consult a physician.<sup>191</sup>

This same label is required to be placed on all containers of fresh, raw shellfish that leave packing or processing plants.<sup>192</sup> Even with these measures, each year a greater number of individuals contract the bacteria through consumption. The following section delineates exactly how more stringent regulation could prevent such illnesses by using recent California regulations as a model of effective means of combatting Vibrio vulnificus.

# IV. CALIFORNIA'S MODEL FOR REGULATION OF RAW OYSTERS TO PREVENT ILLNESS AND INFECTION

Vibrio vulnificus has a presence far greater than the coasts of Florida, as the bacteria touches any area unfortunate enough to get a shipment of oysters from the Gulf of Mexico that are contaminated with the bacteria. In a seven-year study from 2001 to 2008, California reported 828 cases of Vibriosis—though only a few of these were caused by Vibrio vulnificus, as California suffers from a high incidence rate of Vibrio parahaemolyticus.<sup>193</sup> However, in 2003, after two years of increased Vibrio vulnificus cases that resulted in sixteen infections and ten deaths despite increased education measures highlighting the risk of consuming

<sup>193</sup> DIANA S. DOOLEY & RONALD W. CHAPMAN, CAL. DEP'T OF PUBLIC HEALTH, EPIDEMIOLOGIC SUMMARY OF NON-CHOLERA VIBRIOSIS IN CALIFORNIA, 2001-2008 71-72 (2011), *available at* http://www.cdph.ca.gov/programs/sss/Documents/Epi-Summaries-CA-2001-2008-

<sup>&</sup>lt;sup>191</sup> FLA. ADMIN. CODE ANN. § 61C-4.010.

<sup>&</sup>lt;sup>192</sup> § 5L-1.007(9).

<sup>083111.</sup>pdf#page=73 ("V. parahaemolyticus infection causes acute gastroenteritis with fever that usually occurs after an incubation period of 24 hours. Symptoms usually last 1 to 7 days and are often self-limited.").

raw oysters, California decided to pass unprecedented regulation on the sale of oysters harvested in the Gulf of Mexico from April to October.<sup>194</sup>

California's 2003 legislation dramatically restricted the sale of raw oysters from Alabama, Florida, Louisiana, Mississippi, and Texas, the states considered to produce "Gulf oysters."<sup>195</sup> California requires dealers of raw oyster products to refuse those containers of oysters coming from the Gulf states that have not been clearly labeled with harvest location and date.<sup>196</sup> The regulation also requires any raw oysters coming from the Gulf States to be "subjected to an oyster treatment process;" in the event they are not, the oysters must be cooked before being consumed.<sup>197</sup> The FDA has approved several treatment methods for reducing or eliminating Vibrio vulnificus from raw oysters, including: "low-temperature pasteurization, high-pressure processing, and irradiation."<sup>198</sup> The regulations take these precautions one step further and require dealers or restaurants offering raw oysters to refuse Gulf oysters that were harvested from April through October altogether.<sup>199</sup> Such oysters are deemed by California law to be adulterated unless they are properly treated and consistently labeled, and the seller of the raw oyster must have paperwork verifying the oysters were treated.<sup>200</sup>

Part of California's 2003 Gulf oyster legislation involved warning potential consumers of the risks associated with enjoying raw oysters, tailoring the warning to at-risk groups, including those suffering from illness of the liver, cancer, and chronic immune illnesses.<sup>201</sup> The law regulates, in depth, how this

<sup>&</sup>lt;sup>194</sup> Gitika Panicker, Michael L. Myers & Asim K. Bej, *Rapid Detection of Vibrio Vulnificus in Shellfish and Gulf of Mexico Water by Real-Time PCR*, 70 APPLIED & ENVTL. MICROBIOLOGY 498, 506 (2004).

<sup>&</sup>lt;sup>195</sup> CAL. CODE REGS. tit. 17, § 13675(a)(2).

<sup>&</sup>lt;sup>196</sup> *Id.* § 13675(c)(1)-(3)(C).

<sup>&</sup>lt;sup>197</sup> *Id.* § 13675(c)(3)(D) (requiring oysters to be treated in such a manner as to reduce the level of Vibrio vulnificus to an undetectable level).

<sup>&</sup>lt;sup>198</sup> Daniels, *supra* note 59, at 791.

<sup>&</sup>lt;sup>199</sup> CAL. CODE REGS. tit. 17, § 13675(c)(5).

<sup>&</sup>lt;sup>200</sup> Id. § 13675(c)(5)(A)-(B).

<sup>&</sup>lt;sup>201</sup> *Id.* § 13675(b)(1) ("WARNING: THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE (FOR EXAMPLE ALCOHOLIC CIRRHOSIS), CANCER OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE

warning should be provided to the public, requiring a written warning to any person ordering raw oysters, worded in English and Spanish and prominently placed so that potential consumers can easily see the sign prior to finalizing their order.<sup>202</sup> The law delineates the size, coloring, spacing, and font of the warning that must be displayed for raw oysters purchased over the counter.<sup>203</sup> The regulation also requires restaurants serving oysters to have the warning printed on all of the menus listing oysters as available for purchase or, in the alternative, on "tent cards" on the dining tables in the establishment.<sup>204</sup>

A survey conducted approximately a decade after California enacted this legislation studied the effect of the regulations on reported cases of illness and death resulting from Vibrio vulnificus.<sup>205</sup> The study showed that the number of reported cases of Vibrio vulnificus fell from fifty-seven in the years from 1991 to 2002, to four during 2003 through 2010.<sup>206</sup> There was also a marked drop in Vibrio vulnificus deaths after the regulation, from thirty-eight in the years preceding the legislation to one in the seven-year period after the enactment of the strict regulations.<sup>207</sup> The survey credited the success in combatting Vibrio vulnificus to the 2003 regulations, attributing many cases of the illness to raw oysters and effectively showing a reduction-and near elimination-of reported

IMMUNE SYSTEM. If you eat raw ovsters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician."). <sup>202</sup> *Id.* § 13675(b)(1)-(2).

<sup>&</sup>lt;sup>203</sup> *Id.* § 13675(b)(2)(A)-(E) (requiring that the sign be a square that is at least ten inches on each side or a rectangle that measures at least 11 inches high and 8.5 inches wide; the sign has to be printed in contrasting colors with at least one third of an inch of space on each side of the notice; "warning" must be in all bold, upper case letters, underlined, and no smaller than a 35 point font; the first two sentences of the issued warning must be bolded and at least size 30 font type).

<sup>&</sup>lt;sup>204</sup> Id. § 13675(b)(3) (allowing warnings on menus to be shortened to the first two sentences, but still requiring the portion of the warning that addresses those individuals at a higher risk of illness subsequent to consuming raw oysters).

<sup>&</sup>lt;sup>205</sup> Duc J. Vugia et al., Impact of 2003 State Regulation on Raw Oyster-Associated Vibrio Vulnificus Illnesses and Deaths, California, USA, 19 EMERGING INFECTIOUS DISEASES 1276, 1276 (Aug. 2013), available at http://wwwnc.cdc.gov/eid/article/19/8/pdfs/12-1861.pdf.

<sup>&</sup>lt;sup>206</sup> *Id.* at 1278 ("The median annual number of cases dropped from 5.5 (range 1–9; total 57 cases) during 1991–2002, before implementation, to 0 (range, 0-2; total 4 cases) during 2003–2010, after implementation of the 2003 regulation."). <sup>207</sup>*Id*.

cases.<sup>208</sup> The survey did not, however, reflect a significant change in the number of people consuming raw oysters that were available in the state.<sup>209</sup> The success of this California legislation was used as an example by officials proposing a similar federal ban in 2009.<sup>210</sup> According to a California public health official, "[a] similar regulation to restrict the sale of raw summer-harvested Gulf Coast oysters to those treated by postharvest processing, if implemented in Florida, would likely decrease *V. vulnificus* illnesses and deaths due to eating unprocessed raw oysters."<sup>211</sup>

# V. PROPOSAL TO ENHANCE THE HEALTH SAFETY OF BEACHGOERS AND RAW OYSTER CONSUMERS

With sea temperatures on the rise and Vibrio vulnificus on the prowl, the state of Florida faces increased risks of the bacteria along its Gulf Coast as these warm, clear waters are heavily used by the public for swimming and recreational purposes and raw oysters are still a popular food item in many restaurants. This risk is not isolated to the Gulf coast, but stretches to all of Florida's coastlines, as the bacteria crops up in new locales and infects many along the Atlantic coastline of Florida as well. And with over one thousand miles of coastline<sup>212</sup> and a profitable oyster industry,<sup>213</sup> Florida's pull on tourists and residents alike creates a large potential for Vibrio vulnificus outbreaks and a great need for heightened public awareness of the bacteria.

<sup>&</sup>lt;sup>208</sup> *Id.* ("The data strongly suggest that the dramatic and sustained drop in reported raw oyster– associated *V. vulnificus* illnesses and deaths in California was related to the 2003 California regulation that restricts the sale of raw oysters harvested from the Gulf Coast during the 7 warmest months to oysters treated with postharvest processing."). <sup>209</sup> *Id* 

 <sup>&</sup>lt;sup>210</sup> Lyndsey Layton, *Industry, FDA at Odds on Raw Oysters*, WASH. POST (Nov. 10, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/11/09/AR2009110903339.html.
 <sup>211</sup> *Id.* (according to the chief of the Infectious Diseases Branch at the California Department of Public Health).

<sup>&</sup>lt;sup>212</sup> Florida has nearly 1,350 miles of coastline. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2012 225 (2012).

<sup>&</sup>lt;sup>213</sup> "Apalachicola Bay produces 90% of Florida's oysters and 10% of the nationwide supply. Over 2.6 million pounds of oyster meat is harvested annually." *Apalachicola's Fresh Local Seafood*, APALACHICOLA BAY,

http://www.apalachicolabay.org/index.cfm/pageid/101/fuseaction/chamber.categorydisplay (last visited Apr. 17, 2015).

The legal framework discussed above, while not directly addressing the looming problem of Vibrio vulnificus along Florida's coasts and nestled in the state's oyster beds, is a foundational step in the right direction to address the health and safety concerns that the bacteria poses to the public. The federally mandated bacteria testing, as applied by the state, can be tweaked to address the concerns of environmental bacteria as it affects coastal water quality. There can be more stringent enforcement of oyster bed closings in peak Vibrio vulnificus months to reduce the risk of contaminated shellfish reaching the dinner plates of the unaware or risk-taking consumer. More importantly, the public can be made more aware, and the state can take further steps in educating and notifying the public, as to the dangers of Vibrio vulnificus and the times at which they are most likely to come into contact with the illness.

# A. Addition of Vibrio Vulnificus to Bacteria Criteria for Water Quality and Subsequent Testing

Federal and state laws already provide a framework for the regulation of water quality, but these criteria focus solely on pollutants found in coastal waters. Bacteria criteria are leveled at enteric bacteria<sup>214</sup> that are found in waters due to sources of pollution like run-off, discharge, or waste that finds its way into coastal waters. The previously mentioned deficiency in the current bacteria water quality standards is that state regulations do not require the monitoring of coastal waters for environmental bacteria, such as the naturally occurring Vibrio bacteria. This flaw could be remedied by a requirement that the elevated presence of environmental bacteria be considered by the SDS and listed as a criteria for water quality and for subsequent testing. This addition would require little change to the current laws, as the general framework is already provided and water quality already regulated to protect the health of those who partake in the recreational opportunities along Florida's miles of coasts.

<sup>&</sup>lt;sup>214</sup> The federal and state governments mandate testing only for fecal bacteria, like coliform and enterococci bacteria, as a sign that waters are bacterially impaired. FLA. DEP'T OF ENVTL. PROTECTION, *supra* note 124, at 13.

Should legislation be too time consuming or cumbersome to pass, it is also possible to amend the FHBP's protocol to include testing for Vibrio vulnificus. The FHBP's explanation for not testing for the presence of Vibrio vulnificus in recreational coastal waters is that the process is too "difficult and costly."<sup>215</sup> However, new methods to test for Vibrio vulnificus are being studied that make distinguishing between Vibrio and other naturally present environmental bacteria more affordable and accessible.<sup>216</sup> Recently, methods have been studied to test for Vibrio in both coastal waters and oysters that would be "rapid, reliable, and costeffective."<sup>217</sup> This method uses a fluorescent dye that has worked well for other bacteria to achieve test results in under eight hours for both water and oyster samples, a marked improvement from former processes that took three to four days to produce results for Vibrio vulnificus tests.<sup>218</sup> This process has so enhanced the testing procedures for Vibrio vulnificus that commercial tests for the bacteria are now available and can produce results within twenty-four hours.<sup>219</sup>

Further, since the peak seasons for Vibrio vulnificus are widely known, testing weekly or bi-weekly the whole year round, as the FHBP currently requires for fecal bacteria found in the coast via pollutants, would not be necessary. "Rapid detection of [Vibrio vulnificus] in consumable oysters and in coastal water, especially in and around approved oyster-harvesting sites . . . would help reduce the incidence of illness and fatality that result from ingestion of raw shellfish or from exposure to coastal water."220 This proposed testing would provide the state of Florida advance warning of Vibrio vulnificus both in its popular coastal waters and oyster harvesting regions, thus enabling the state to

<sup>&</sup>lt;sup>215</sup> Bibler, *supra* note 173, at 9.

<sup>&</sup>lt;sup>216</sup> Several decades ago, the process of isolating Vibrio vulnificus from other naturally occurring flora and bacteria in the ocean incorporated Colistin-Polymyxin B-Cellobiose agar (CPC agar), a form of antibiotics. James D. Oliver et al., Use of Colistin-Polymyxin B-Cellobiose Agar for Isolation of Vibrio vulnificus from the Environment, 58 APPLIED & ENVIRONMENTAL MICROBIOLOGY 737, 738 (1992).

 <sup>&</sup>lt;sup>217</sup> Panicker, Myers & Bej, *supra* note 194, at 506.
 <sup>218</sup> *Id*.

<sup>&</sup>lt;sup>219</sup> Vibrio sp. Detection and Identification in Foods, RAPIDMICROBIOLOGY,

http://www.rapidmicrobiology.com/test-method/detection-and-identification-of-vibrio-species-infood/ (last visited Apr. 17, 2015) ("An example of a commercially available PCR-based method for pathogenic Vibrio detection is the BAX® System Real-Time PCR Assay ... [which is] able to detect the three most important species, V. cholerae, V. parahaemolyticus and V. vulnificus .....").  $^{220}$  Id

prevent illness by detecting contaminated batches of oysters before they hit the hands of consumers.

# B. Restricting the Sale of Raw Oysters During Peak Vibrio Vulnificus Seasons – Applying the California Model

Florida's battle with Vibrio vulnificus appears to be intensifying, with more reported cases each year. California implemented its strict raw oyster legislation after battling sixteen cases and ten deaths resulting from Vibrio vulnificus outbreaks in a span of two years,<sup>221</sup> but these numbers closely resemble the statistics for one year of reported cases of the bacteria and resulting illnesses in Florida.<sup>222</sup> As the oceans warm and bacteria populations grow, the state of Florida should consider maximizing the protection of public health by enacting stronger oyster protection legislation pursuant to the precautionary principle discussed previously. With some laws already in place, Florida could easily amend this legislation or enact new regulations, possibly following the California model that has markedly reduced reported cases of infection and death at the hands of Vibrio vulnificus. While the NSSP guidelines are the primary source and inspiration for Florida's shellfish regulation, the guidelines are meant to establish only the minimum necessary requirements for the protection of consumers.<sup>223</sup>

Florida has already established the Shellfish Harvesting Program to monitor water quality in and around oyster beds, but the program currently uses fecal bacteria as indicators for dangerous pathogens.<sup>224</sup> Florida should consider adding Vibrio vulnificus bacteria as a criteria for water quality, which would trigger testing for its presence in harvesting areas, in order to prevent potential illnesses before the oysters even leave the bays. Advancements in testing protocols<sup>225</sup> for Vibrio vulnificus appear to have made it easier to isolate the bacteria from others that naturally occur in coastal waters, and the quick turn-

<sup>&</sup>lt;sup>221</sup> Panicker, Myers & Bej, *supra* note 194, at 506.

<sup>&</sup>lt;sup>222</sup> In 2008, Florida reported fifteen cases of infection and five deaths; in 2009, these values rose to twenty-four cases and seven deaths. In 2011, fatalities in Florida were at an all-time high, with thirty-five reported infections and thirteen deaths. *Information on Vibrio Vulnificus, supra* note 24. <sup>223</sup> NAT'L SHELLFISH SANITATION PROGRAM, *supra* note 137, at 10-11.

<sup>&</sup>lt;sup>224</sup> FLA. DEP'T OF ENVTL. PROTECTION, *supra* note 124, at 7.

<sup>&</sup>lt;sup>225</sup> Panicker, Myers & Bej, *supra* note 194, at 498.

around time for results would allow harvesting areas to be quickly classified as restricted or closed to prevent contaminated shellfish from reaching consumers. Mandating and implementing testing for Vibrio vulnificus specifically, and responding quickly to change the status of these harvesting areas would also allow Florida to more expediently and efficiently comply with, or even render unnecessary, NSSP's requirement that harvesting areas be closed, states warned, and recalls orchestrated after two or more cases of Vibrio vulnificus-associated illnesses have been discovered.<sup>226</sup>

Like California, Florida already regulates the seasons during which oysters can be harvested from certain areas. Unlike California, however, which requires the treatment or refusal of oysters from the Gulf of Mexico from April until the end of October,<sup>227</sup> Florida only closes or conditionally allows harvesting from areas it considers at high risk for Vibrio vulnificus from July to the end of September.<sup>228</sup> The CDC has noted that over eighty-five percent of Vibrio vulnificus cases are reported in the months between May and October.<sup>229</sup> Florida's seasonal restrictions thus fail to include three months in which Vibrio vulnificus cases are known to peak, leaving a gap in the protection of consumer health. Adopting similar seasonal restriction months as California, perhaps from May to the end of October, to close or conditionally approve harvesting areas where populations of Vibrio vulnificus are known to peak, coupled with testing for the bacteria, would allow Florida to combat oyster-associated illness rates.<sup>230</sup> Reported cases of the bacteria associated with the consumption of raw oysters in Florida could be dramatically reduced, if not eliminated, as shown in California.

Should Florida fail to be persuaded in extending seasonal restrictions to cover the full peak season of the bacteria, the state could also consider requiring post-harvest treatment of oysters pulled from at-risk areas. Like California, Florida could require FDA-approved post harvest treatments, including low-

<sup>&</sup>lt;sup>226</sup> NAT'L SHELLFISH SANITATION PROGRAM, *supra* note 137, at 23.

<sup>&</sup>lt;sup>227</sup> CAL. CODE REGS. tit. 17, § 13675(c)(5).

<sup>&</sup>lt;sup>228</sup> FLA. ADMIN. CODE ANN. 68B-27.019.

<sup>&</sup>lt;sup>229</sup> *Vibrio Vulnificus, supra* note 12.

<sup>&</sup>lt;sup>230</sup> Restricting or closely regulating oyster harvesting during the known peak seasons from May to October would be less restrictive than the eight-month total ban the FDA suggested placing on Gulf oysters in 2009. Press Release, *supra* note 161.

temperature pasteurization, and high-pressure processing.<sup>231</sup> These methods are accredited with reducing, if not eliminating entirely, the risk of the bacteria in oysters.<sup>232</sup> Post-harvest treatment would avoid the industry harm that has been associated with harvesting bans during extended seasonal periods.<sup>233</sup> There are several paths Florida could take, following the example of California, in saving the lives and limbs of oyster consumers.

## C. Requiring Public Notification and Warnings During Peak Vibrio Vulnificus Seasons

Important in implementing each of the aforementioned proposed courses of action is how Florida uses these methods to notify the public of the presence of Vibrio vulnificus in coastal waters and warn individuals of the risks associated with exposing open wounds to or ingesting the bacteria. Regulation coupled with public notification is key to successfully tackling the challenge that Vibrio vulnificus presents to the state. Adapting the legislation already in place to fit the demands of the Vibrio bacteria would allow Florida to make strides in the direction of increasing awareness and vigilance within the public realm to reduce illness.

> 1. Coast Posts - Tailoring Beach Advisories to Vibrio Vulnificus

The BEACH Act already requires,<sup>234</sup> and Florida has in place,<sup>235</sup> an existing procedure for public notification of bacteria levels in recreational coastal waters that exceed mandated water criteria standards. The current system, which involves notifying the media, posting the results of water samplings on county health department websites, and posting advisory signs on the beach where failing

<sup>&</sup>lt;sup>231</sup> Daniels. *supra* note 59, at 791.

<sup>&</sup>lt;sup>232</sup> Id.

<sup>&</sup>lt;sup>233</sup> Kevin Begos et. al., U.S. FDA BAN ON RAW OYSTERS WILL PUT THOUSANDS OF GULF COAST MEN AND WOMEN OUT OF WORK, AND THREATEN OTHER REGIONS 1 (Oct. 22, 2009), available at http://www.ecsga.org/Pages/Issues/Human Health/FDA OysterBanPressRelease10-09.pdf (fearing loss of jobs and harmful industry impacts stemming from a federal ban on all Gulf coast oysters for eight months each year).

<sup>&</sup>lt;sup>234</sup> 33 U.S.C. § 1346(a)(1)(B).
<sup>235</sup> Bibler, *supra* note 173, at 9.

samples were obtained, hinges on fecal bacteria to indicate the presence of dangerous pathogens.<sup>236</sup> This system could easily be tweaked to apply to Vibrio vulnificus bacteria. At the root of all possible solutions for addressing the concern spawned by this bacteria is a testing procedure for Vibrio vulnificus that isolates this natural pathogen from others that float along the coasts. If the state were to mandate testing specifically for the bacteria, the FHBP could then conduct these tests as part of their bi-weekly sampling program<sup>237</sup> and post the results accordingly. Testing the coast for the bacteria would provide advance warning of the bacteria, allowing the media to be notified before tragedy falls upon any uninformed victim, thus provoking education and discussion of the bacteria's presence as opposed to panic that evolves from news stories of horrific injuries and loss of life.

An equally potent source of public notification exists in the sign postings along the shore and beach access points where Vibrio vulnificus may be discovered prowling along the surf. The current advisories that are posted for elevated levels of fecal bacteria are a solid foundation.<sup>238</sup> requiring only minor changes to make them suitable for apprising the public of risks associated with diving into waves speckled with Vibrio bacteria. The FHBP should consider, however, employing the methodology California uses in its consumer advisories—that is, tailoring the general beach warnings to those individuals that face a higher chance of contracting an illness from interacting with the bacteria in the surf and identifying them in the text of the warning.<sup>239</sup> Bv targeting the advisory to those at risk. Florida would promote awareness in those that face heightened levels of danger while leaving those healthy individuals to enjoy their time on the state's coasts with more knowledge of the bacteria, but less baseless fear. Creating an advance warning system for Vibrio vulnificus would allow the public to make better health decisions in their recreational activities and reduce the rate of infection.

<sup>&</sup>lt;sup>236</sup> Id.

<sup>&</sup>lt;sup>237</sup> Id. at 3.

<sup>&</sup>lt;sup>238</sup> See supra text accompanying notes 171-74.

<sup>&</sup>lt;sup>239</sup> See supra text accompanying note 201.

Should testing for the specific bacteria be deemed impractical, the state may consider a mandated warning and notification system employing these same methods during the known peak season of Vibrio vulnificus. While actually testing the water prior to generating public awareness is preferable, both to avoid speculation and unnecessary avoidance of coastal recreation when the bacteria may not even be at issue, the old adage does say that it is better to be safe than sorry. If the state's health departments were to generate media buzz about Vibrio season and the risks that the bacteria poses to certain individuals, people may be inspired to do their own research and avoid the water until there was no risk, or take proper precautions to protect themselves from wound exposure to saltwater.<sup>240</sup> Posting signs along the coast based on the possibility that the bacteria may be lurking within the waves may give individuals the opportunity to consider the consequences of wound exposure if they believe themselves to be at risk. Although this form of notification involves speculation, it would be effective in getting the word out about a bacteria that few know poses any threat.<sup>241</sup>

2. Raw Oyster Warnings – Tailoring Advisories to Those Most at Risk Pursuant to the California Model

Paramount in Florida's efforts to educate consumers of the risks associated with consuming raw oysters that may be contaminated with Vibrio vulnificus is the consumer advisory that the state requires on containers and displayed in restaurants with raw oysters on the menu.<sup>242</sup> While it is safe to say that this system of warning is effective in providing some awareness of the risk this menu item may pose, small changes to the existing advisory could significantly increase awareness for those individuals that should abstain from the food altogether. Here again, amending Florida's current warning system to reflect the California advisory<sup>243</sup> would allow the state to more directly warn at-risk consumers away from the perilous entrée. It would be beneficial to add to the existing advisory individuals with diabetes, as this condition has been widely accepted as one that

<sup>&</sup>lt;sup>240</sup> The Florida Department of Health recommends individuals to "[a]void exposure of open wounds or broken skin to warm salt or brackish water, or to raw shellfish harvested from such waters." *Information on Vibrio Vulnificus, supra* note 24.

<sup>&</sup>lt;sup>241</sup> See supra note 85 and accompanying text.

<sup>&</sup>lt;sup>242</sup> FLA. ADMIN. CODE ANN. § 61C-4.010.

<sup>&</sup>lt;sup>243</sup> See supra text accompanying note 201.

puts individuals at a higher risk for contracting an illness after exposure to the bacteria.<sup>244</sup> The state should also consider more stringent regulations of the sign, including size and coloring, to make the advisory as prominent as possible, as practiced by California.<sup>245</sup>

Florida should also consider, along the lines of the California regulation, mandating a warning at locations that sell raw oysters over the counter.<sup>246</sup> Not all raw oysters are consumed within the confines of a restaurant, and those individuals that take the shellfish home for consumption may not read or notice a label affixed to the container in which the product is packed. Posting a noticeable warning at the point of sale would give consumers an extra chance to take heed and protect themselves from possible illness. For those consuming the dish in restaurants, Florida should consider requiring more than the consumer warning be visible in a viable location,<sup>247</sup> but consider mandating that the warning be either on the menu or on tent cards on the table, as required by California's 2003 legislation.<sup>248</sup>

#### VI. CONCLUSION

Vibrio vulnificus-associated illnesses are not isolated to the state of Florida. As the oceans warm, the populations of Vibrio vulnificus thrive and spread to areas that have previously not had to worry about the lurking dangers of the pathogens.<sup>249</sup> However, Florida is particularly vulnerable to the risks of the bacteria, as the state's coasts draw millions of visitors each year<sup>250</sup> and its oyster

http://www.visitfloridaonline.com/article\_visit.htm (last visited Apr. 17, 2015).

<sup>&</sup>lt;sup>244</sup> See supra text accompanying notes 74, 100.

<sup>&</sup>lt;sup>245</sup> See supra text accompanying note 203.

<sup>&</sup>lt;sup>246</sup> CAL. CODE REGS. tit. 17, § 13675(b)(2).

<sup>&</sup>lt;sup>247</sup> *Id.* § 61C-4.010.

<sup>&</sup>lt;sup>248</sup> *Id.* § 13675(b)(3).

<sup>&</sup>lt;sup>249</sup> Jessica Forres, Vibrio Bacteria a Bigger Threat to Swimmers than Sharks as Northern Waters Warm, NATURAL RES. NEWS SERVICE (May 22, 2007),

http://www.dcbureau.org/20070522711/natural-resources-news-service/vibrio-bacteria-a-biggerthreat-to-swimmers-than-sharks-as-northern-waters-warm.html ("For example, Vibrio wound infections have increased from one victim reported to Maryland public health authorities in 2000 to 13 reported [in 2006] in that state.").

<sup>&</sup>lt;sup>250</sup> Approximately seventy-five million people visit Florida per year. David G. Hallstrom, Sr., *Florida Travel and Tourist Information*, VISIT FLORIDA,

production is a significant source of revenue,<sup>251</sup> both of which are avenues of infection for Vibrio vulnificus. On average, between 2008 and 2014, approximately thirty people have suffered from Vibrio vulnificus infections and illnesses in the state of Florida each year, and an average of nine individuals have succumbed to these bacterial illnesses.<sup>252</sup> Strikingly, despite the rate of infection and illness caused by the bacteria and the fact that these cases have been under a system of national surveillance since 2007,<sup>253</sup> many individuals remain unaware of the risks associated with wading out into coastal waters or slurping back a raw oyster. This lack of awareness creates a system where individuals put themselves at risk without intention because they are not aware of the dangers against which they need to guard themselves. This lack of awareness is especially problematic in the case of immunocompromised individuals, as these individuals are regarded as eighty times more likely to become a Vibrio victim.<sup>254</sup>

There is little direct regulation regarding the risk of Vibrio vulnificus in Florida. While water quality is monitored per federal and state legislation, the resulting system of testing and reporting fails to isolate environmental bacteria like Vibrio. The FDA and ISSC, however, do require direct regulation of Vibrio bacteria in shellfish, especially those hailing from the Gulf of Mexico. And while Florida has enacted the required minimum legislation as proposed by the NSSP guidelines, individuals are still contracting Vibrio-related illnesses via consumption of shellfish from the Gulf, not just in Florida, but in regions that receive importations of Gulf oysters. At the root of the problem is the lack of notification, as no advance warning system for Vibrio exists to notify those who should think twice before diving into the coast or, aside from vague consumer advisories, ordering a plate of raw oysters.

California has taken the NSSP guidelines a step further than what is strictly required in regulating Gulf oysters. The state has placed an embargo of sorts on raw oysters during peak Vibrio vulnificus seasons, requiring either the

<sup>&</sup>lt;sup>251</sup> Shellfish, supra note 136.

<sup>&</sup>lt;sup>252</sup> These calculations are based on the figures distributed by the Florida Department of Health. *See Information on Vibrio Vulnificus, supra* note 24.

 $<sup>^{253}</sup>_{254}$  Id.

 $<sup>^{254}</sup>$  *Id*.

treatment of raw oysters before consumption or the refusal to accept the shellfish.<sup>255</sup> California also ensures the notification of at-risk individuals as to the dangers of consuming raw oysters, directing their advisories to these individuals in particular.<sup>256</sup> These regulations, while seemingly harsh, have dramatically reduced the incidence rate of reported cases of Vibrio in the state.

The proposals discussed in this article, like mandating testing of recreational waters and oyster harvesting areas for Vibrio vulnificus and applying the California model of raw oyster regulation during the bacteria's peak seasons, could reduce the number of individuals who fall prey to Vibrio vulnificus in Florida each year. Instituting these measures would necessarily address the root of the problem-the lack of an advance warning system. Testing waters and preventing the consumption and sale of contaminated shellfish during peak Vibrio seasons would pave the way to the creation of a public warning system, as state officials would have specific knowledge of the presence of the bacteria without the unnecessary tragedies of illness and infection that once gave rise to such information. Directing warnings to at-risk individuals, as California requires in their consumer advisories, would also work to enhance public knowledge of the dangers of the bacteria and allow those individuals to make informed decisions that could directly impact their health, taking some of the mystery out of the bacteria and lifting some of the burden of researching it from the shoulders of the public.

When asked about dangers hidden within the depths of Florida's coasts, many individuals' minds will spring to sharks, the ultimate marine predator. Few individuals, if any, will consider the bacteria that lurk, quite as naturally as sharks, within the crests of the waves they enjoy. However, sharks only killed three people worldwide in 2014,<sup>257</sup> whereas Vibrio vulnificus killed seven people in Florida alone.<sup>258</sup> The loss of life and limb that Vibrio vulnificus causes can be reduced or eliminated, if the California model is any example, and the state of

<sup>&</sup>lt;sup>255</sup> See generally CAL. CODE REGS. tit. 17, § 13675.

<sup>&</sup>lt;sup>256</sup> See supra text accompanying note 201.

<sup>&</sup>lt;sup>257</sup> George H. Burgess, *ISAF 2014 Worldwide Shark Attack Summary*, INT'L SHARK ATTACK FILE, https://www.flmnh.ufl.edu/fish/sharks/isaf/2014Summary.html (last visited Apr. 17, 2015).

<sup>&</sup>lt;sup>258</sup> Information on Vibrio Vulnificus, supra note 24.

Florida should consider taking the aforementioned steps to protect the public from the unseen danger that the bacteria presents.