July 2021 • Volume 20:3

The SandBar

Legal Reporter for the National Sea Grant College Program

Supreme Court Sides with Georgia Against Florida in Long-Running Water Rights Dispute

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ISSN 1947-3966 NSGLC-21-02-03 *July 2021*
ISSN 1947-3974

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Recommended citation: Author's Name, *Title of Article*, 20:3 SANDBAR [Page Number] (2021).

Cover page photograph of a Apalachicola Bay, Florida, courtesy of Steven Gray.

Contents page photograph of an Egret, courtesy of Smuzz Photography.

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Contents

Supreme Court Sides with Georgia Against Florida in Long-Running Water Rights Dispute

Betsy Lee Montague[1]

Sunrise over the Apalachicola Bay, courtesy of Anoldent Photography.

At one time, Apalachicola Bay produced 90% of the oysters in Florida. In 2012, the oyster population essentially collapsed.[2] The State of Florida claimed that low flows from interstate waters was to blame. The U.S. Supreme Court recently dismissed a lawsuit brought by the State of Florida against the State of Georgia concerning the proper apportionment of interstate waters.[3] In a unanimous opinion written by Justice Amy Coney Barrett, the Court rejected Florida's argument that Georgia was consuming more than its fair share of water from an interstate network of rivers in the Apalachicola-Chattahoochee-Flint River Basin. The ruling means Georgia may continue using water at its current rate, and Florida will need to look elsewhere to aid the Apalachicola oyster industry.

Background

The Apalachicola-Chattahoochee-Flint River Basin spans more than 20,000 square miles in Georgia, Florida, and Alabama. The Basin contains three rivers. The Chattahoochee River and the Flint River are critical sources of water for Georgia, particularly for the Atlanta area and Georgia's agricultural industry. The third river, the Apalachicola River, flows south through the Florida Panhandle and supports a wide variety of plant and animal species, including oysters.

The states have disputed the Atlanta metropolitan area's increased use of water from the Chattahoochee River for years.[4] Following the third regional drought in just over ten years, Florida brought suit against Georgia in the U.S. Supreme Court in 2013. Because the dispute was between two states, it fell under the Court's original jurisdiction. Therefore, the case went straight to the Supreme Court, rather than working its way through lower courts. Florida claimed Georgia's overconsumption of water caused low flows in the Apalachicola River, which in turn harmed Florida's oyster fisheries and river ecosystem. As a remedy, Florida sought an order that would require Georgia to reduce its consumption of Basin waters. The Court appointed two different Special Masters, both of which recommended that the Court deny Florida's requested relief. Florida filed exceptions to the Special Masters' recommendations.

Burden of Proof

Due to the competing state interests at issue, the burden of proof for Florida was much greater than the burden ordinarily borne by a private party seeking an injunction. In this case, the Court said Florida had to make two showings to obtain an equitable apportionment of the water, allowing the state to restrict Georgia's consumption in favor of its own. First, Florida had to prove a threatened or actual injury of serious magnitude caused by Georgia's water consumption. Second, Florida was required to demonstrate that the benefits of an apportionment to Florida would "substantially outweigh" the harm that might result to Georgia. The Court noted that because Georgia and Florida are both riparian states, meaning they follow the common law of riparian rights to water, the guiding principle of the dispute would be ensuring that both states have an "equal right to make a reasonable use" of the Basin water.[5]

Florida asserted that Georgia's overconsumption of Basin waters caused two separate injuries: the collapse of its oyster fisheries and harm to its river ecosystem. Although the Court agreed with Florida that the collapse of its oyster sales constituted an injury of "serious magnitude," the Court nevertheless disagreed as to the cause of the collapse. While Florida blamed the collapse on Georgia's unreasonable agricultural water consumption, Georgia pointed to a more direct cause—Florida's mismanagement of its oyster fisheries. In particular, Georgia claimed that Florida caused the collapse by overharvesting oysters and failing to replace harvested oyster shells.

After reviewing the record of witnesses and evidence, the Court agreed with the Special Master that Florida failed to prove by clear and convincing evidence that the collapse of its oyster fisheries was caused by Georgia's overconsumption. Specifically, the Court stated that Florida's own witnesses and documents revealed that Florida allowed unparalleled levels of oyster harvesting in the years before the collapse, and also that other factors like changing rainfall patterns and multiyear droughts may have played a role. The Court held that Florida "has not shown that it is 'highly probable' that Georgia's alleged overconsumption played more than a trivial role in the collapse of Florida's oyster fisheries" and, therefore, failed to carry its burden of proving causation.[6]

Conclusion

The Court overruled Florida's exceptions to the Special Masters' Reports and dismissed the case. Georgia may therefore continue consuming water from the Basin as it has been. In closing, Justice Barrett did, however, emphasize that "Georgia has an obligation to make *reasonable* use of Basin waters" in order to conserve the increasingly scarce resource.[7] Georgia Governor Brian Kemp called the decision a "resounding victory for Georgia and a vindication of years-long effort by multiple governors and attorneys general here in the Peach State to protect our citizens' water rights."[8] Nikki Fried, Florida Agriculture Commissioner, on the other hand, found the decision "disappointing for the thousands of families whose livelihoods depend" on the river basin.[9]

The Court's holding leaves Florida unable to argue its case further, as there is no opportunity to appeal. Nevertheless, equitable apportionment disputes over water between states may be refiled if the case concerns changed circumstances. Florida's ability to file the case again may change in the future "should conditions worsen and Florida provides new evidence" according to Craig Pendegrast of Taylor English Duma, an environmental lawyer and former counsel to the Apalachicola Chattahoochee Flint Stakeholders.[10]

Aside from future litigation, the states and residents may have other ways to conserve the water resource. For example, ACF Stakeholders is a private, non-profit organization of representatives from Georgia, Florida, and Alabama that came together and developed a "Sustainable Water Management Plan."[11] Released in 2015, the Sustainable Water Management Plan offers technical water-sharing solutions to resolve the water war outside of litigation.[12] In response to the Court's decision, ACF Stakeholders Chairman Phil Clayton felt that the group could now "shift the focus back to the development of an equitable stakeholder-supported water sharing plan for the ACF Basin."[13] Therefore, the future of the Basin waters remains open.

This article was adapted from an NSGLC blog post published April 15, 2021.

Endnotes

1 2022 J.D. Candidate, University of Mississippi School of Law.

2 Brendan Farrington, *Florida Shuts Down Oyster Harvesting In Apalachicola Bay Through 2025*, Pensacola New Journal (Dec. 16, 2020).

3 Florida v. Georgia, No. 142, 2021 WL 1215718 (U.S. Apr. 1, 2021).

4 Micah Goodwin, *Florida v. Georgia: U.S. Supreme Court Addresses Decades-Long Water Conflict*, JD Supra (Apr. 5, 2021).

5 *Florida*, 2021 WL 1215718 at *4.

6 *Id.* at *6.

7 *Id.* at *10 (emphasis added).

8 Katheryn Tucker, *How Justice Amy Barrett Ended the Florida v. Georgia Water War—With a Caveat*, Law.com (Apr. 2, 2021).

9 Ellen M. Gilmer & Jennifer Kay, *Supreme Court Hands Win to Georgia in State Water War (3)*, Bloomberg Law (Apr. 1, 2021).

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11 ACT Stakeholders Inc.

12 Lara Fowler, *No April Fool's Joke for Florida: Water Rights Case is Dismissed*, SCOTUSblog (Apr. 1, 2021).

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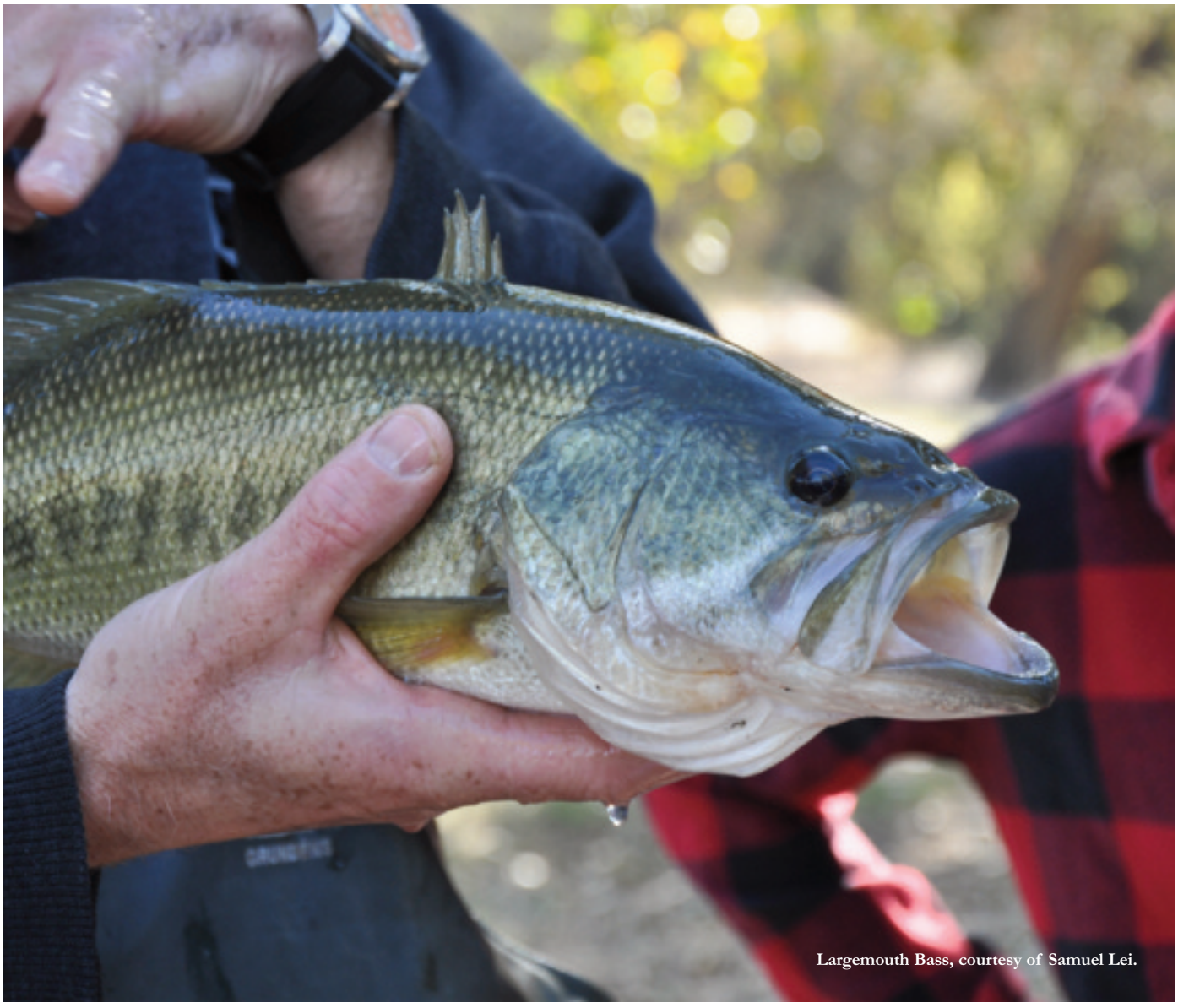
USDA Expands Aquaculture Eligibility Under Disaster Relief Program

Catherine Janasie[1]



Largemouth Bass, courtesy of Samuel Lei.

Severe winter weather in early 2021 negatively impacted aquaculture growers from the Great Lakes to the Gulf Coast. Due to the losses sustained, fish farmers began to inquire if the U.S. Department of Agriculture (USDA) Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish (ELAP) Program applied to them. For instance, Illinois fish farmers growing Largemouth Bass applied for USDA ELAP funds to try and save their farms.[2] However, according to the farmers, the county Farm Service Agency (FSA) directors claimed ELAP only covers losses to bait fish and game fish, and not fish raised as food. This response from the FSA led the aquaculture industry to reach out to the agency to discuss the impacts on growers of fish for human food, resulting in a change in position by the FSA.

ELAP Overview

The USDA ELAP program is administered by the FSA. The program is meant to cover losses caused by adverse weather or other conditions, but not covered by other USDA disaster assistance programs. For farm-raised fish, ELAP covers two specific types of losses. First, ELAP provides compensation for the loss of feed purchased or harvested for the producer's farm-raised fish. Second, ELAP provides compensation for the death of certain farm-raised fish.[3] For farm-raised fish, eligible adverse weather and loss conditions include, but are not limited to: earthquakes, floods, hurricanes, tidal surges, tornados, and volcanic eruptions; for feed losses, excessive wind; and for death losses, excessive heat and certain freezes.

In regards to death losses, ELAP was traditionally applied only to bait and game fish.[4] However, the ELAP regulations finalized in 2014 allowed for the possibility for additional types of farm-raised fish to be covered by the program. The rule states:

> (h) For fish to be eligible to generate payments under ELAP, the fish must be produced in a controlled environment and the farm-raised fish must: … (2) For death losses: (i) Be bait fish, game fish, *or another aquatic species deemed eligible by the Deputy Administrator* that are propagated and reared in a controlled environment.[5]

Therefore, the 2014 ELAP Rule allowed for additional fish species to be covered by the ELAP program. However, as of the time of the 2021 winter storms, additional species had not been added through this discretionary provision.

FSA Expands the ELAP Program

Due to outreach by the aquaculture community, the FSA announced two specific expansions to ELAP on May 13, 2021.[6] First, FSA determined that freeze would be an eligible loss condition for the program in both 2021 and subsequent years. Second, FSA expanded the eligible species to include both 1) any species of aquatic organisms grown as food for human consumption and 2) fish raised as food for fish that are consumed by humans.[7] Importantly, eggs and larvae are not eligible for the program.

The FSA also provided some clarification on some additional requirements. For purposes of ELAP, an eligible farm-raised fish must be raised in an "aquaculture facility," which the FSA has defined as a commercial operation on 1) private property and 2) in a controlled environment. As to the private property requirement, there have been questions about whether leases of state water bottoms would satisfy the requirement. The FSA clarified this issue, stating that "leased property with readily identifiable boundaries" qualifies as long as the leaseholder has control over the waterbed and "does **not** have control over **only** a column of water."[8]

To meet the controlled environment requirement, the producer must control, maintain, and harvest in accordance with normal practice and manage potential hazards, such as by instituting predator and diseases controls. In addition, the producer must plant or seed the species in a way that protects and contains the species, such as in a container, wire basket, net pen, on a rope, or any other similar device.[9]

To meet the controlled environment requirement, the producer must control, maintain, and harvest in accordance with normal practice and manage potential hazards, such as by instituting predator and diseases controls.

Additional Application Requirements

As of June 1, 2021, eligible aquaculture producers can apply to ELAP for losses that occurred on or after January 1, 2021. Normally, the FSA requires producers to file a notice of loss within 30 calendar days of the date when the loss becomes apparent to the producer. However, if the loss occurred before June 1, 2021, the FSA is waiving the 30-day notice requirement. The deadline to file claims for 2021 is January 31, 2022, and the producer may be asked to show documentation that substantiated the eligible loss event and shows the operation's beginning and ending inventory.[10] The producer will also need to submit documentation that show they operate a commercial operation. These documents could include sales contracts, invoices, or receipts, fish marketing statements, ledgers of income, or income statements of deposit slips.[11] Producers with questions on eligibility or the application process can direct their questions to their local USDA Service Center.[12]

Endnotes

1 Sr. Research Counsel, National Sea Grant Law Center.

2 Personal communication from IL-IN SG Extension Agent.

3 17 CFR § 1416.102(h).

4 Memorandum, U.S. Dep't of Agric., Adding Food Fish and Other Aquatic Species to 2021 and Subsequent Years ELAP 1 (May 13, 2021).

5 *Id.* § 1416.102 (emphasis added).

6 Press Release, Farm Service Agency, USDA Expands Aquaculture Disaster Assistance to Include Fish Raised for Food (May 13, 2021).

7 U.S. Dep't of Agric., *supra* note 3, at 3.

8 *Id.* at 4 (emphasis in the original).

9 *Id.* at 2-3.

10 Farm Service Agency, *supra* note 5.

11 U.S. Dep't of Agric., *supra* note 3, at 6.

12 Local USDA Service Centers.

Courts Weigh in on Horseshoe Crab Harvesting in Cape Romain

Amiah Henry[1]

Horseshoe Crab, courtesy of Karen Parker.

Pharmaceutical companies around the world use horseshoe crab blood in vaccine development. The white blood cells of the crab are drawn for endotoxin bacterial testing, which, if not detected, can be deadly. Environmentalists, however, worry about how the harvest of the species impacts the environment and the protection of threatened or endangered wildlife.

The U.S. District Court for the District of South Carolina recently ruled on a preliminary injunction request filed by several environmental organizations to stop the harvest of horseshoe crabs at Cape Romain National Wildlife Refuge (Refuge) in South Carolina.[2] The plaintiff alleged that the U.S. Fish and Wildlife Service (FWS) violated several federal laws, including the Endangered Species Act (ESA), by allowing the harvest of horseshoe crabs. In the shadow of the COVID-19 pandemic and the resulting vaccine development, the court ruling highlights the delicate balance between vaccine safety measures and environmental protection.

Background

In the lawsuit, the environmental organization alleged three threatened and protected animal species—red knots, piping plovers, and loggerhead sea turtles—are being negatively affected by the commercial harvesting of horseshoe crab in the Refuge. The Refuge, which runs along 22 miles of the South Carolina coast, was first designated as a migratory bird refuge in 1932. Today the Refuge has grown to encompass 66,000 acres of bays and estuarine emergent wetlands and barrier islands. In 1991, the federal government entered into a 99-year lease with the state of South Carolina acquiring all of the state's interest "within the boundaries of the Refuge" or contiguous and "adjacent to the easterly boundary and fronting on the Atlantic Ocean at mean low tide."[3] The lease is "subject to [ ] [t]he right of the State of South Carolina to authorize the taking of shellfish, finfish, and other salt water species within the refuge boundary."[4]

Horseshoe crabs spawn on the beaches of Cape Romain's islands each year between April and June. For a number of years, horseshoe crabs have been commercially harvested in the intertidal zone of the Refuge's islands. The horseshoe crabs' blood is used to test the safety of injectable pharmaceutical drugs and vaccines. The white blood cells of the crab, which contain limulus amebocyte lysate (LAL), is drawn for endotoxin bacterial contamination testing. Endotoxins, a fever-causing toxic bacterial protein, can be deadly; therefore, the FDA requires all products produced by pharmaceutical, biomedical, and biotechnology companies to be endotoxin free.

Charles River Laboratories, one of only four companies approved by the FDA to produce and distribute LAL, has been purchasing the horseshoe crabs from independent contractors in Cape Romain for over 30 years. They use the LAL assay for the bacterial endotoxin testing. For the process, they concentrate and rupture the cell membrane to disintegrate the blood of the Atlantic horseshoe crab and create a product which can detect the equivalent of a grain of sand's worth of bacteria in an Olympic sized pool of the material being tested. More than 80 million LAL assay tests are performed annually and they have never provided a false-negative result.

Since 2003, the FWS has closed three islands in Cape Romain—Marsh Island, White Banks, and Sandy Point—to boat landings from February 15th to September 15th to protect nesting birds. After learning that horseshoe crab harvesting was continuing on Marsh Island despite the closure, the FWS sent harvesters letters notifying them of alternative harvesting locations and granted special permits to harvest outside of usual operating times in 2014. As recently as 2016, independent contractors who provide horseshoe crabs for Charles River were issued letters by the FWS reminding them of the closed islands and asking them to use other areas of the Refuge.

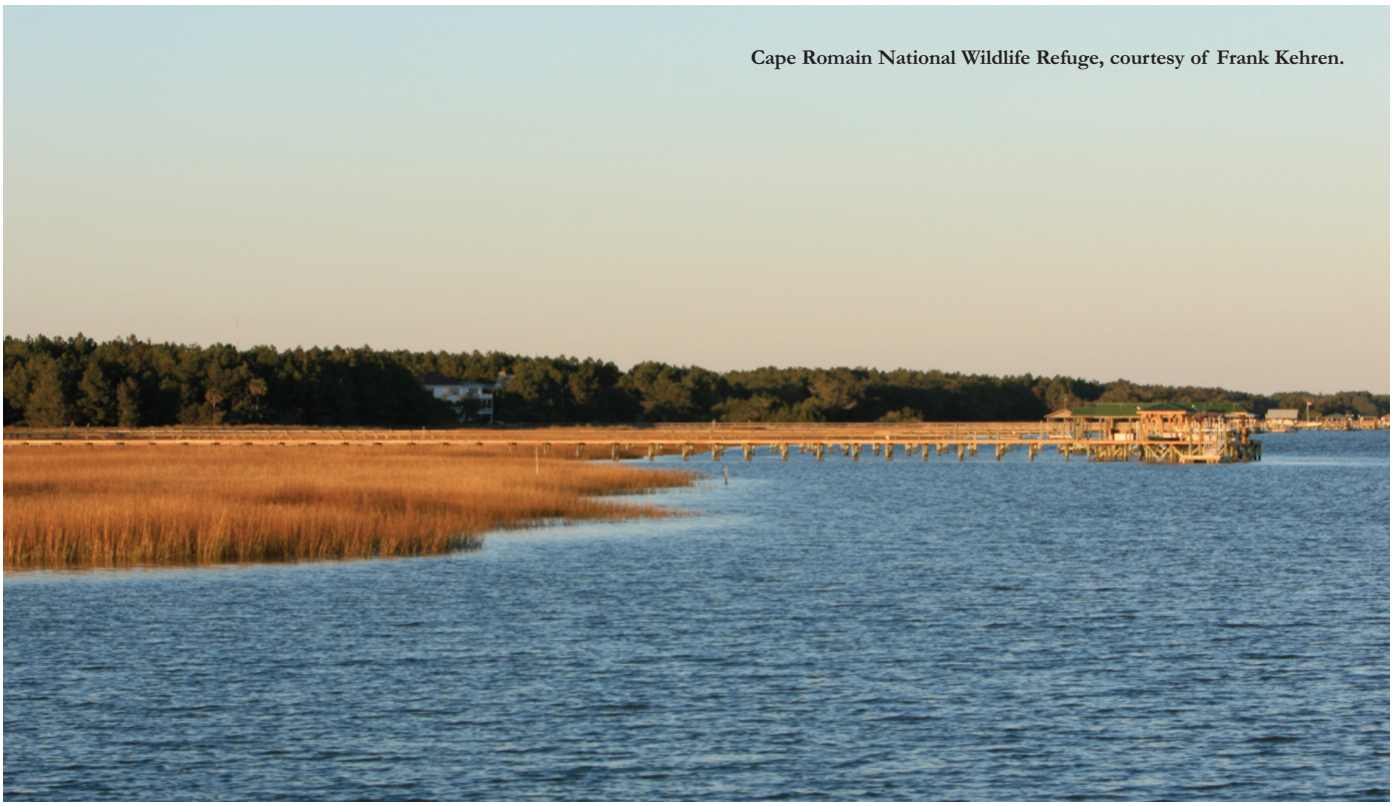
The Defenders of Wildlife filed suit challenging the FWS's authorization of horseshoe crab harvest in the Refuge. The suit alleged that harvesting threatens the breeding, feeding, and shelter abilities of certain protected species. The piping plover is sensitive to human disturbance; therefore, the harvesting of the horseshoe crab by independent contractors, especially in the closed season, would damage the species solitude of shelter and breeding. The plaintiff further asserted that up to thirty percent of the horseshoe crabs die after harvesting and the remaining crabs have a lower survival rate and are less likely to lay eggs. This directly impacts the endangered loggerhead sea turtle, as the horseshoe crab is an important prey species. Additionally, the red knot is reportedly seeing a decline in their visits to the Refuge where the horseshoe crab's nutrient rich eggs are a critical food source.

Preliminary Injunction

The environmental organizations sought a preliminary injunction on several grounds, the first three under the Refuge Improvement Act and the last two under the ESA. First, they contended that the FWS's authorization of the horseshoe crab harvest violates the Refuge Improvement Act by failing to 1) determine the compatibility of the harvesting with the Refuge's purpose, 2) issue special use permits for commercial activity, and 3) ensure the Refuge's management is not in fact undermining its purposes. Additionally, the plaintiff claimed the FWS violated the ESA and the Migratory Bird Treaty Act by not reinitiating consultation on the Cape Romain Comprehensive Conservation Plan after the threatened species were listed. In order to succeed on a preliminary injunction, a party must show a likelihood of success on the merits, a likelihood of irreparable harm, the balance of equities tips in its favor, and the injunction is in the public interest.

In examining the likelihood of success on the merits, the court found that the plaintiff made a clear showing on the claim that the FWS's authorization for harvest violates the Refuge Improvement Act by failing to prohibit commercial horseshoe crab harvesting except by special permit. Under the Act's regulations, commercial activities at a national wildlife refuge require a special permit. In this instance, the FWS did not require the harvesters to obtain a special permit. The court rejected the FWS's argument that the 1991 lease specifically reserved to the State of South Carolina the right to authorize commercial activity.

In assessing the irreparable harm if a preliminary injunction was not granted, the plaintiff argued that the red knot would be irreparably harmed, as the harvest of horseshoe crabs reduces or eliminates the amount of horseshoe crab's eggs, a critical food source for the red knot during its migration. Further, its members would suffer irreparable harm to their enjoyment of the refuge because



Cape Romain National Wildlife Refuge, courtesy of Frank Kehren.

they would not be able to view the threatened red knot species. The court agreed that the plaintiff clearly showed irreparable harm to the environment if the preliminary injunctive relief was not granted.

Finally, the court noted that a party seeking a preliminary injunction must also assert that the balance of equities, while within their favor, is one that is in the public's interest. The court found that the public interest weighed in favor of issuing the preliminary injunction because endangered and threatened species are at issue. Further, it is in the public interest for the FWS to comply with applicable regulations. In addition, the injunction would not prevent Charles River from applying for a special permit or harvesting horseshoe crabs elsewhere. The court granted the plaintiff's request for a preliminary injunction in part, which means that the commercial harvesting of horseshoe crabs on the Refuge is prohibited unless authorized by special permit.

Emergency Stay of Preliminary Injunction

Following the district court ruling, Charles River filed an appeal to the U.S. Court of Appeals for the Fourth Circuit requesting an emergency stay on the preliminary injunction.[5] In its emergency motion, Charles River questioned the decline of the red knot population, citing the FWS's draft recovery plan reporting the bird population as sturdy. Additional evidence of hundreds of the inhabitant birds seen in recent photographs were also highlighted. Charles River further asserted that after extraction, when the horseshoe crabs are returned to the water, the morality rate for the crabs is approximately four percent. They further claimed urgency in the matter, as the best and possibly last harvesting window in 2021, based on the lunar calendar and tides, fell between Sunday, May 23rd to Friday, May 28th. If the injunction were to continue, Charles River would miss the last harvesting window of the season.

On May 24, 2021, the Fourth Circuit granted the motion for the emergency stay.[6] This means the independent contractors or companies may continue to harvest while the appeal is pending in the Fourth Circuit. The delicate balance between vaccine safety measures and environmental protection continues to be an interesting topic, but we will have to await final decision on the matter from the courts.

Endnotes

1 2023 J.D. Candidate, Roger Williams University School of Law.

2 Defs. of Wildlife v. U.S. Fish & Wildlife Serv., No. 2:20-CV-3657-BHH, 2021 WL 1909917 (D.S.C. May 12, 2021).

3 *Id.* at 3.

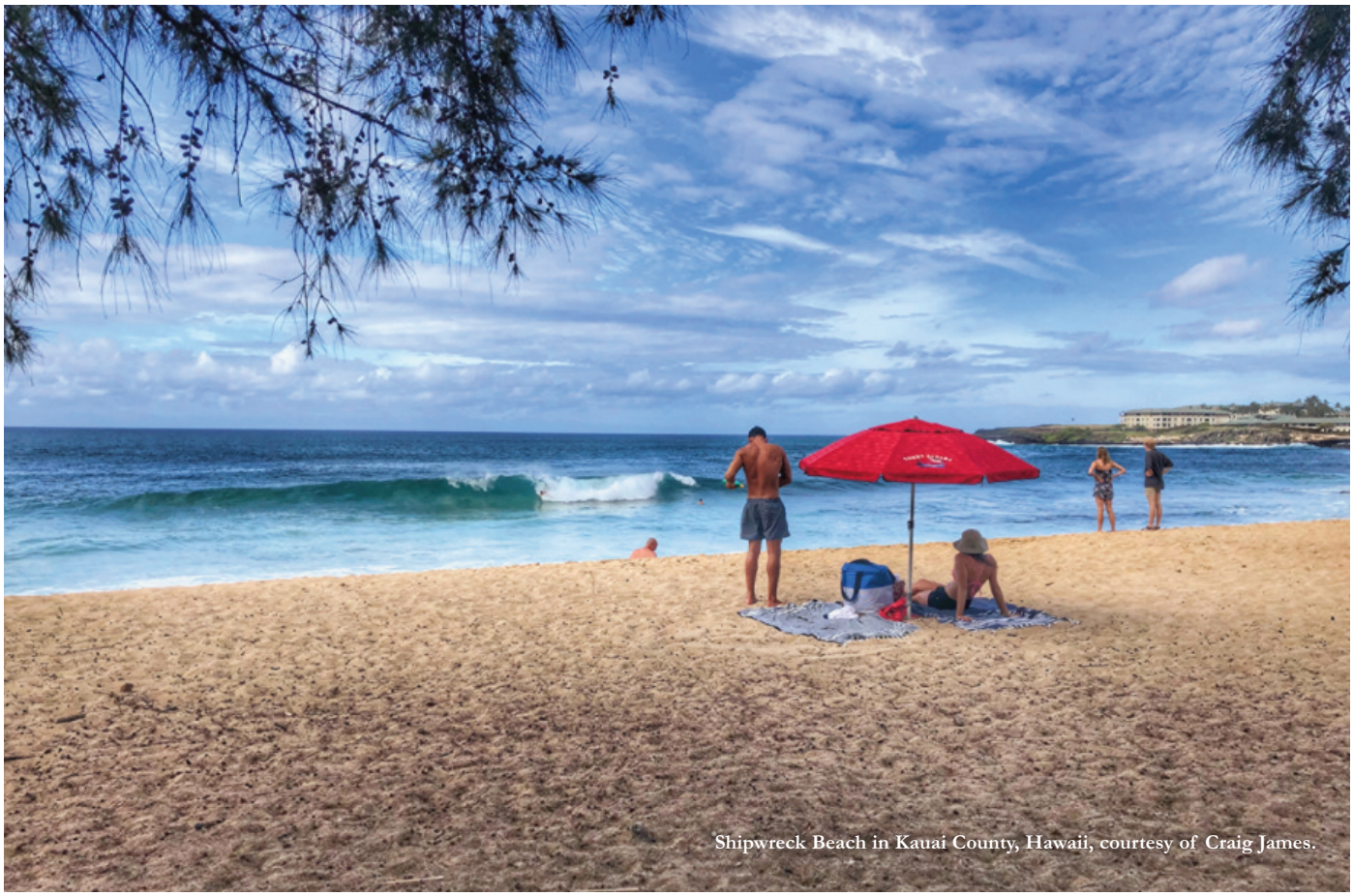
4 *Id.* at 11.

5 Motion for an Emergency Stay Pending Appeal, Charles River Labs Int. Inc. et al. v. Defs. of Wildlife, No. 21-1589, (4th Cir. May 17, 2021).

6 Corrected Order, Defs. of Wildlife v. Charles River Labs Int. Inc. et al., No. 21-1589 (4th Cir. May 24, 2021).

Screening Sunscreen: FDA Regulation and State Bans

Katherine Hupp[1]



Shipwreck Beach in Kauai County, Hawaii, courtesy of Craig James.

Oxybenzone and octinoxate, two ultraviolet light filters, are common ingredients in over-the-counter (OTC), or non-prescription, sunscreens. In recent years, the ingredients have come under scrutiny for their impacts on humans and the environment. For example, wash-off from sunscreen near coral reefs contributes to higher concentrations of oxybenzone and octinoxate than generally found in nature, which may have fatal consequences for these vital natural ecosystems.[2] Recent studies suggest that oxybenzone and octinoxate inhibit coral development and resiliency, which leads to coral bleaching and die-off and potential disruption of entire reef ecosystems. Furthermore, sunscreen users may be at risk as oxybenzone and octinoxate are suspected endocrine disrupters.[3]

Recently, federal, state, and local governments have taken steps to regulate OTC sunscreens containing these ingredients. Due in part to recent legislation, the Food and Drug Administration (FDA) is considering the ingredients' environmental impact and evaluating whether sunscreen companies must submit a new drug application (NDA) before bringing many OTC sunscreens to market. Below is an overview of the FDA's actions, as well as a look at several state and local attempts to regulate certain OTC sunscreens.

Beach in Saint Thomas of the U.S. Virgin Islands, courtesy of Luis Alveart.

FDA Sunscreen Regulation

The FDA regulates cosmetics and OTC drugs through its authority under the federal Food, Drug, and Cosmetic Act.[4] For decades, companies have been able to market OTC sunscreens containing potentially harmful ingredients without getting NDA approval from the FDA first.[5] Typically, companies may market OTC drugs without submitting an NDA but are subject to a "final monograph." A final monograph is the "rule book" which dictates the acceptable ingredients, dosage strength, labeling requirements, and testing procedures for various categories of drugs.[6] If a drug does not satisfy the requirements of the relevant final monograph, the drug's sponsor must submit an NDA to the FDA for market approval.

The FDA published a final sunscreen monograph in 1999. The 1999 monograph listed 16 active ingredients "generally recognized as safe and effective" (GRASE) for sunscreens.[7] Oxybenzone and octinoxate made the list. The 1999 monograph permits OTC sunscreens containing a maximum concentration of 6% oxybenzone or 7.5% octinoxate to forego NDA approval. This 1999 sunscreen monograph was stayed and never became effective; however, the FDA's discretionary sunscreen enforcement policy, which allows the agency to take action if a product does not meet certain parameters, adheres to the monograph.

In February 2019, nearly twenty years after oxybenzone and octinoxate first attained GRASE status, the FDA proposed a rule intended to "put into effect a final monograph" for OTC sunscreens.[8] In the proposed rule, the FDA acknowledged it did not have enough information to determine whether twelve ingredients listed in the original 1999 monograph, including oxybenzone and octinoxate, are GRASE. The rule explained that the FDA sought further information from the industry on the safety of these ingredients. The FDA noted that increased sunscreen use and higher labeled SPF values may increase chemicals' transdermal absorption rate and thus toxicity potential in humans. In addition, public comments received during the 2019 rulemaking "raised concerns about the potential impacts from sunscreens containing oxybenzone or octinoxate on coral and/or coral reefs."[9] The FDA missed the deadline to publish the final rule.

The CARES Act

In March 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)—legislation primarily aimed at pandemic relief. The CARES Act contains a provision requiring the FDA to update the list of designated safe active ingredients for OTC sunscreens. Consequently, the FDA no longer has the option to continue to postpone updates to its decades-old stayed sunscreen monograph; it must evaluate how changes in sunscreen use over time affect its original understanding of oxybenzone's and octinoxate's safety rating for human use. Significantly, the CARES Act scraps the time-intensive notice-and-comment monograph publication process and replaces it with a more streamlined and efficient administrative order process. Moreover, the CARES Act instructs the FDA to adopt a new sunscreen order by September 27, 2021. The order will designate whether, given evolving human behavior and scientific understanding, oxybenzone and octinoxate are GRASE.

The CARES Act-mandated sunscreen order will result in a major federal action with potentially significant environmental consequences; therefore, the National Environmental Policy Act (NEPA) requires environmental review. Accordingly, in May, the FDA issued a notice of intent to prepare an environmental impact statement (EIS) to determine the potential environmental impacts of a revised OTC sunscreen active ingredient list.[10] The environmental analysis could influence whether the FDA approves oxybenzone and octinoxate as GRASE.

Sunscreen Bans

Recent efforts by environmental organizations, local governments, and even private businesses echo the environmental concerns raised in comments on the FDA's 2019 proposed final monograph rule.[11] In 2018, the Center for Biological Diversity (CBD) petitioned the FDA to ban oxybenzone and octinoxate in sunscreen and personal care products.[12] In the alternative, CBD asked the FDA to engage in a Section 7 consultation under the Endangered Species Act (ESA). Section 7 of the ESA contains consultation provisions. The consultation provisions apply to federal agency actions and aim to ensure that any proposed action by an agency would likely not jeopardize or destroy or adversely modify a species' critical habitat.[13]

Presently, the state of Hawaii and the U.S. Virgin Islands are the only U.S. territories that have enacted legislation restricting the sale or distribution of sunscreens containing oxybenzone or octinoxate. Both state laws cite studies measuring the chemicals' impacts on coral and marine life.[14] The broader-scoped U.S. Virgin Islands ban took effect in March 2020. It prohibits the *use or possession* of OTC sunscreen products containing oxybenzone, octinoxate, or octocrylene. Hawaii's law, on the other hand, which took effect January 1, 2021, largely applies to retailers; it prohibits the act of selling or distributing OTC sunscreens containing oxybenzone or octinoxate. Pending legislation in Hawaii proposes to expand the list of prohibited ingredients.[15]

Similarly, the City Commission of Key West passed an ordinance in February 2019 making it unlawful in Key West to sell, offer for sale, or distribute for sale OTC sunscreen containing oxybenzone, octinoxate, or both after January 1, 2021.[16] Like the bans in Hawaii and the Virgin Islands, Key West's law cited the chemicals' harmful impact on the coral and marine life that protect Key West's shoreline. But unlike the bans in Hawaii and the Virgin Islands, Key West's ban never came into force. In July 2020, Florida Governor Ron DeSantis signed a bill that reversed the Key West ban and expressly preempted local governments in Florida from regulating OTC sunscreens.[17]

Conclusion

If the FDA finds that sunscreens containing oxybenzone or octinoxate must procure NDA approval before becoming marketable, sunscreen manufacturers may consider reformulating their products altogether to escape NDA obligations. Furthermore, given the more efficient process by which the FDA can now modify its final list of approved ingredients, businesses may proceed cautiously in reformulating their products in case the FDA or state or local governments expand the list of prohibited OTC sunscreen ingredients in the future.

Endnotes

1 2022 JD Candidate, Florida State University College of Law.

2 *See* C.A. Downs, et al., *Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands*, 70 Archives Env't Contamin. & Toxicology 265 (2016).

3 *See, e.g.,* Susie Suh, et al., *The Banned Sunscreen Ingredients and Their Impact on Human Health: A Systematic Review*, 59 Int. J. Dermatol. 1033 (2020).

4 21 U.S.C. § 301 *et seq*.

5 *Id.*

6 NDA approval ensures the drug is safe and that the benefits of the drug outweigh the risks. *New Drug Application*, U.S. Food & Drug Admin. (June 10, 2019).

7 A GRASE determination enables marketers to forego the NDA process before marketing OTC sunscreens with GRASE ingredients. Sunscreen Drug Products for Over-the-Counter Human Use, Preliminary Regulatory Impact Analysis, U.S. Office of Policy, Planning & Legis. 10 (2019).

8 Sunscreen Drug Products for Over-the-Counter Human Use, 84 Fed. Reg. 6204 (proposed Feb. 26, 2019) (to be codified at 21 C.F.R. pts. 201, 310, 347, 352).

9 Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use, 86 Fed. Reg. 26224 (notice issued May 13, 2021).

10 *Id.*

11 In 2018, CVS began removing oxybenzone and octinoxate from its store-brand sunscreen with SPF 50 and lower. CVS Health, 2018 Corporate Social Responsibility Report: Better Health, Better Community, Better World, 13, 61, 73 (2018).

12 Center for Biological Diversity, Petition to Ban the Active Ingredients Oxybenzone and Octinoxate in Sunscreens and Other Personal Care Products (May 24, 2018).

13 16 U.S.C. § 1536(2).

14 Haw. Rev. Stat. § 342D-21 (2018); Virgin Isl. Code tit. 27, ch. 9, § 305h (2019).

15 *See* S.B. 132, 31st Leg. Sess. (Haw. 2021) (to be codified at Haw. Rev. Stat. § 342D-21) (to also ban avobenzone and octocrylene beginning January 1, 2023).

16 Key West, Fl., Code of Ordinances ch. 26, art. VII, §§ 26-311 (2019) (Ord. No. 19-03, § 1, 2-5-2019).

17 Amendment to the Florida Drug and Cosmetic Act, S.B. 172, 2020 Reg. Legis. Sess. (Fla. 2020) (codified as amended at FLA. STAT. § 499.002(7) (2020)).

New Developments in Offshore Wind

Caroline Heavey[1]

Since January, the Biden administration has taken several steps toward encouraging offshore wind energy development. During his first week in office, President Biden issued Executive Order 14008 (E.O. 14008), which articulated goals for offshore wind energy development.[2] In March, the President announced a plan to achieve those goals. In April, the administration repealed a Trump-era opinion that hampered offshore wind energy development. Then, in May, the administration announced approval for the largest commercial-scale offshore wind farm to date. The administration's latest steps focus on developing an offshore wind energy plan, expediting offshore wind energy permitting, and approving major wind farms in offshore federal waters.

Renewable Energy Executive Order

E.O. 14008 lays the framework for the development and management of renewable energy on public lands and in offshore waters. The order sets a goal for renewable energy to be doubled by 2030, while ensuring robust protection for U.S. lands, waters, and biodiversity. Another major objective of the renewable energy plan is to create "good-paying, union jobs."

The E.O. recognized the Secretary of the Interior's oversight authority of the process for identifying new sites and authorizing permits for renewable energy production on public lands and in offshore waters. The E.O. authorized a task force to aid in increased renewable energy production. While the Secretary of the Interior has oversight, the agency is required to consult with other heads of relevant agencies, including the Secretary of Commerce, the Administrator of the National Oceanic and Atmospheric Administration (NOAA), and State and Tribal authorities. Further, the E.O. requires the Secretary of the Interior to coordinate with Tribal leaders for the development and management of energy resources located on Tribal lands.

A Plan of Action

In March, the Biden administration announced a series of "bold actions" to "catalyze offshore wind energy, strengthen the domestic supply chain, and create good-paying, union jobs," to effectively "position America to lead a clean energy revolution."[3] President Biden convened several members of the administration, namely Secretary of Transportation Pete Buttigieg, Interior Secretary Deb Haaland, Energy Secretary Jennifer Granholm, Commerce Secretary Gina Raimondo, and National Climate Advisor Gina McCarthy, to meet with state and industry leaders to identify a framework to achieve the objectives enumerated in E.O. 14008. The administration articulated three major steps to support rapid offshore wind energy development and job creation:

(1) Advance ambitious wind energy projects to create good-paying, union jobs;

(2) Invest in American infrastructure to strengthen the domestic supply chain and deploy offshore wind energy; and

(3) Support critical research and development and data-sharing.

Good-Paying, Union Jobs

Toward the goal of creating good-paying, union jobs, President Biden announced a new wind energy area located in the New York Bight. It is predicted to support 25,000 construction and development jobs between 2022-2030, 7,000 jobs in the local community spurred by the development, 4,000 operations and maintenance jobs annually, and potentially 2,000 community jobs in the years following development. The Interior Department's Bureau of Ocean Energy Management (BOEM) will publish a Proposed Sale Notice that will be followed by a public comment period and a lease sale later this year or early 2022.

Furthermore, the Departments of the Interior, Energy, and Commerce announced a shared goal to deploy 30 gigawatts (GW) of offshore wind energy by 2030, while protecting biodiversity and promoting ocean co-use. The 30 GW target will trigger $12 billion in capital investments, support potentially 40,000 jobs by 2030, and generate enough power to meet the demand of 10 million American homes for a year. It will avoid 78 million metric tons of CO_2 emissions. To reach this goal, BOEM plans to advance new lease sales and complete the review of sixteen Construction and Operation Plans by 2025, unlocking more than 19 GW of offshore wind energy. The new supply chains will require more than $500 million in port upgrade investments, factories for windfarm components, and construction of offshore turbine installation vessels. If the target is achieved, it will unlock the potential for 110 GW by 2050.

Invest in American Infrastructure

The Department of Transportation (DOT) Maritime Administration announced $230 million for Port Infrastructure Development Program projects that support shore-side wind energy projects, including storage areas, laydown areas, and docking of wind energy vessels. DOT will consider how proposed projects can most effectively address climate change and environmental justice imperatives when reviewing the applications for funding. The Department of Energy Loan Programs Office announced $3 billion for the offshore wind industry through the Title XVII Innovative Energy Loan Guarantee Program to scale offshore wind and create jobs.

Research and Development and Data-Sharing

The Department of Energy and New York State Energy Research and Development Authority created the National Offshore Wind Research and Development Consortium, which will award $8 million to fifteen offshore wind research and development projects. The projects include support structure innovation, supply chain development, electrical systems innovation, and mitigation of use conflicts, reducing barriers and costs for offshore wind development. NOAA partnered with Ørsted, an offshore wind development company, to share physical and biological data in Ørsted-leased waters within the United States' jurisdiction. This agreement paves the way for future data-sharing agreements between NOAA and other developers. NOAA also solicited research proposals to support $1 million in grant funding for objective community-based research in the Northeast to further understand the impact of offshore renewable energy on the ocean, local communities, and economies, as well as opportunities to optimize ocean co-use.

Reversal of Trump-Era Hurdles to Offshore Energy

In April, the Biden administration rescinded a Trump-era legal opinion that made offshore wind energy development difficult. The Trump-era opinion sought to prohibit "all unreasonable interference" and erred on the side of less, or *de minimis*, interference with reasonable uses, effectively hampering offshore wind because "certain wind energy activities would cause unreasonable interference."[4] The Interior Department's Solicitor's Office issued a new opinion that, like the Trump-era opinion, highlighted the importance of striking a balance between the different factors in making the determination. However, unlike the Trump opinion that emphasized free movement of fishing and military vessels, the new opinion emphasized the potential benefits of offshore wind development, such as environmental protection and conservation of natural resources along the Outer Continental Shelf.[5]

The new opinion allows for wide discretion when determining the siting for projects, which arguably was constrained by the Trump-era policy. Furthermore, the opinion emphasized a "fair return" to the United States on any lease or easement granted. The opinion relies on the Outer Continental Shelf Lands Act, which provides guidance as to how the Secretary may grant a lease, easements, or right-of-way for activities, including the transmission of renewable wind energy.

Approval of the First Major Wind Farm in Federal Waters

In May, the Biden administration announced final approval for Vineyard Wind, the nation's first commercial-scale offshore wind farm. Vineyard Wind is a $2.8 billion project that calls for up to eighty-four turbines to be installed twelve nautical miles off the coast of Martha's Vineyard, Massachusetts. It is predicted to generate 800 megawatts of electricity, dwarfing the two existing wind farms that together produce forty-two megawatts. Electricity generated by Vineyard Wind will travel via cables buried six feet below the ocean floor to Cape Cod, connect to a substation, and feed into the New England grid. Construction is expected to begin this summer, and it is expected to begin delivering energy in 2023. A dozen other East Coast offshore wind projects are currently under federal review.

Conclusion

The Biden administration is using American energy and infrastructure policy to create new jobs, open new supply chains, and combat climate change through the expansion of offshore wind energy. The shift will be led by a "whole-of-government" approach, involving key stakeholders in the development and scaling process. The expansion of offshore wind energy is the first step toward Biden's clean energy economy.

Endnotes

1 2022 J.D. Candidate, University of Mississippi School of Law.

2 Exec. Order No. 14,008, 86 Fed. Reg. 7,619, 7,624 (Jan. 27, 2021).

3 Fact Sheet: Biden Administration Jumpstarts Offshore Energy Projects to Create Jobs, Pres. Docs. (Mar. 29, 2021).

4 U.S. Dep't of the Interior, M-Opinion 37059 on Secretary's Duty to Prevent Interference with Reasonable Uses of the Exclusive Economic Zone, the High Seas, and the Territorial Seas in Accordance with Outer Continental Shelf Lands Act Subsection 8(p), Alternate Energy-related Uses on the Outer Continental Shelf (Dec. 14, 2020).

5 U.S. Dep't of the Interior, M-Opinion 37067 on Secretary's Duties under Subsection 8(p)(4) of the Outer Continental Shelf Lands Act When Authorizing Activities on the Outer Continental Shelf (Apr. 9, 2021).

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Littoral Events

2021 Floodplain Management Association Annual Conference

September 7-10, 2021
(Virtual)

For more information, visit: https://floodplain.org/page/AnnualConference

Oceans 2021

September 20-23, 2021
San Diego, CA (and Virtual)

For more information, visit: https://global21.oceansconference.org

American Fisheries Society Annual Meeting

November 6-10, 2021
Baltimore, MD

For more information, visit: https://afsannualmeeting.fisheries.org