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Regulatory Hurdles Impede Zika Control

Communities Need the Freedom to Deploy the Most Effective Tools against Dangerous Vector-Borne Diseases

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Ever since the discovery that the mosquito-transmitted Zika virus can cause serious birth defects, policy makers have been trying to figure out what to do to stop the spread of this horrible virus. In recent months, Zika has been detected in Florida and may well spread to other states. Some have suggested that bringing back the pesticide DDT would solve the problem in the United States and abroad.[1] While DDT has proven a valuable tool around the world in fighting malaria and continues to have useful applications, it does not offer an easy answer to Zika or other mosquito-transmitted illnesses. Rather than bank on a specific product or approach, policy makers should focus on removing regulatory hurdles that undermine the effectiveness of local vector control programs.

Although outbreaks of mosquito-transmitted disease are a global problem, the battle in the United States is largely fought by local vector control experts, who are charged with protecting communities as threats emerge. In collaboration with federal agencies and university researchers, local government officials are best positioned to take the lead in developing situation-specific control programs, applying various technologies as needed. Unfortunately, federal policies deny access to useful pesticides and inhibit the development of new pest-control technologies that local officials need to combat insect-transmitted diseases.[2]

From Malaria to Zika. Zika is one of many vector-borne diseases that have emerged in the United States in recent years as a serious public health challenge. Initially, it was believed that Zika simply causes mild, short-term illnesses, but now there is increasing evidence that it causes microcephaly in babies born from infected mothers and Guillain-Barré syndrome in infected adults. Microcephaly is a serious and disfiguring birth defect that causes babies to be born with small heads and underdeveloped brains, resulting in serious developmental problems. Guillain-Barré syndrome is a condition in which the body's immune system attacks the peripheral nervous system, creating a range of symptoms from numbness and tingling to paralysis, and potentially death in severe cases.[3]

Unfortunately, Zika is just one of many dangerous insect-borne diseases that threaten public health in the United States. In 1999, the West Nile virus appeared in New York City, and since then, it has caused nearly 2,000 deaths and more than 20,000 cases of serious and debilitating neuroinvasive disease.[4] According to the Centers for Disease Control and Prevention (CDC), ticks cause 20,000 to nearly 30,000 cases of Lyme disease in humans

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each year and transmit numerous other illnesses such as babeisosis, which is similar to malaria.[5] The potential for the reemergence of dengue in the United States is also a concern. It is already a significant problem in South America, and has appeared in the U.S. in recent years.[6]

Globally, vector-borne illnesses—from malaria to dengue to Zika—present major health threats, particularly in less developed nations, where people reside in homes that are open to the environment, such as huts and homes without screened windows. During the 1990s and into the new millennium, global malaria cases skyrocketed, while environmental activist groups advocated a global ban on DDT, and world governments considered the ban under the International Convention on Persistent Organic Pollutants (known as the POPs Treaty).[7] Meanwhile, hundreds of millions of people—mostly children in Africa—were getting sick, and many dying, from mosquito-transmitted malaria that could be controlled in good measure with strategic use of DDT.

Indoor residential spraying (IRS) of DDT drives malaria carrying mosquitoes away from human populations, limiting the spread of malaria. That meant spraying interior walls of homes in nations where many lacked windows and screens to keep out mosquitoes. Moreover, DDT repels even DDT resistant mosquitoes, so IRS programs worked even where the mosquitoes had developed DDT resistance.[8]

Accordingly, a coalition of public policy organizations fought the ban and advocated for the freedom for communities to deploy valuable tools in the fight against dangerous vector-borne diseases—in this case the freedom to deploy DDT and other useful vector-fighting tools.[9] After many years of debate and controversy, parties to the POPs Treaty voted in favor of allowing limited use of DDT. Rather than approving widespread spraying in the environment, DDT was allowed for indoor residential spraying.

Indoor residential spraying programs have proven particularly valuable because *Anopheles* mosquitoes, which carry malaria, often feed at night while people are sleeping. In addition, humans and mosquitoes are the only malaria hosts, which means infected mosquitoes can pass the infection to humans and infected humans can pass it to mosquitoes. Birds and other wildlife cannot harbor the virus. Therefore, if the human-mosquito link is broken, it could become possible to eradicate the disease altogether.

Allowing communities freedom to deploy indoor residential spraying of DDT has greatly reduced transmission. Medical researchers provide some details in the *American Journal of Tropical Medicine and Hygiene*:

> During the past decade, IRS [indoor residential spraying] has been implemented successfully in southern African countries, and DDT has been used successfully for IRS in Mozambique, South Africa, and in parts of Swaziland, Eritrea, Ethiopia, and Madagascar. … Malaria had been controlled using IRS with DDT in Kwa-Zulu Natal, an epidemic-prone province in South Africa, from 1946–1995. During the malaria transmission season of 1991–1992, there were only 600 reported cases of malaria. However, because of growing environmental concerns and the presence of

> DDT in breast milk, South Africa substituted synthetic pyrethroids for DDT in 1996. *An. funestus* quickly reemerged (probably after entering from Mozambique) and were found to be resistant to pyrethroids without cross-resistance to DDT. From 1999–2000, 40,700 cases of malaria were reported. After DDT was reintroduced, the number of reported cases diminished rapidly, with 17,500 reported cases in 2001 and 3,500 reported cases in 2002.[10]

CDC Division of Vector-Borne Diseases Director Lyle R. Petersen told *The New York Times* that DDT may have a role in the battle against Zika as it has for malaria, but did not advocate widespread outdoor uses. Strategic indoor residential spraying of DDT could be particularly valuable to help control Zika in the developing world.[11] And where there are widespread disease outbreaks, it might be used in urban areas outdoors. However, the scenario in developed nations is very different, because well-sealed homes with screens largely keep mosquitoes outside and public health budgets are larger, so outbreaks can be controlled with other pesticides and measures.

In the United States, public health officials spray pesticides outdoors on a strategic basis as part of larger vector control programs. Spraying can be effectively deployed to control imminent health threats.[12] For example, CDC officials credited the spraying of a chemical called *naled* with halting a Zika virus outbreak in Miami in 2016. According to officials, this spraying was a critical part of a successful program to stop the spread of disease in Miami's Wynwood district. Locally transmitted Zika appeared there in June and has since disappeared after spraying followed by application of larvicides to potential mosquito breeding grounds. "This outbreak would have kept going without the aerial spraying," the CDC's Petersen explained.[13]

In addition, after screening Zika patients, Florida health officials also discovered one locally transmitted case of dengue, the spread of which was halted thanks in part to quick vector control operations.[14] Spraying may be necessary again in the future—and is ongoing in nearby Miami Beach, where Zika continues to be detected in humans and mosquitoes because mosquitoes can continue to become infected as long as humans harbor the virus.

Still, suggestions that spraying pesticides—DDT or other products—can act as a silver bullet are overly optimistic and belie many challenges that must be managed. So while it is true that pesticide spraying can be helpful, regular widespread spraying is not always effective. It can contribute to the development of pesticide-resistant mosquitoes, and may have adverse impacts on non-target species. Resistance can be managed if there are new pesticides being developed and where vector control can rotate between various products. Unfortunately, there are not many pesticide options. In any case, mosquito control efforts generally focus on a wide range of approaches, from clearing breeding grounds and applying larvicides to strategic spraying when disease appears in adult mosquito populations.

Solutions Start at the Local Level. Ultimately, mosquito control must focus on situation-specific scenarios, which vary greatly from one community to another. Every region has unique features that impact mosquito control approaches. Factors that come into play include climate, topography, local mosquito species, and disease incidence. For example, challenges in hot and humid South Florida are vastly different from those in frigid Michigan.

The various vector-borne diseases also create unique challenges and require different control strategies. For example, West Nile virus is very difficult to eradicate because it is transmitted not only to humans and mosquitoes but to birds and other wildlife as well. Therefore, even when human transmission is relatively low, it will remain in wildlife. In addition, many humans will carry the West Nile virus without ever knowing it because its impacts on some people are minimal. As a result, eradication of West Nile is extremely difficult, if not impossible, using current technology. In contrast, humans and mosquitoes are the primary hosts for the parasite that causes malaria, which means if we break the link between those mosquitoes and humans, we could theoretically eradicate the world of the malaria parasite.

Different types of mosquitoes, their habits, and the human environment in which they operate create different challenges that require different solutions as well. The *Aedes aegypti* mosquito, which can transmit Zika, *dengue, and* chikungunya, presents unique problems because it thrives in urban environments and bites during daytime.

In a recent journal article, Pasteur Institute entomologist Paul Reiter details the varied and considerable challenges in controlling the *Aedes aegypti mosquitoes.* These species breed in tiny amounts of water found in "tree-holes, plant axils, fruit husks, rock-holes and other small natural containers," and breed and thrive in urban environments within a wide range of containers from discarded tires to saucers found under plant pots. To complicate matters more, these mosquitoes lay their eggs in many different places, laying a few here and there at numerous sites.[15]

Rather than wait for larvae to develop into adult mosquitoes and then spray pesticides, vast effort must be made to address these breeding grounds. Reiter proposes an aggressive campaign to eliminate breeding sites and apply pesticides at potential breeding sites that cannot be eliminated. Because they lay eggs in so many places, the female *Aedes aegypti* mosquitoes would likely visit some of the treated sites and be killed by the pesticides. Of course, such campaigns are hard to maintain over the long haul, but could help get disease under control, until we develop other technologies, such as effective vaccines or even sterile genetically modified mosquitoes.

In a nutshell, the challenge posed by Zika is complicated. Hence, the best solutions will develop where there is an open marketplace of ideas, where vector control officials can study, discuss, debate, and test options at the local, national, and international levels—including collaboration and information sharing through organizations such as the American Mosquito Control Association, universities, the CDC, and global organizations. To facilitate this process, lawmakers should make policy reforms to allow the development of new technologies and reduce impediments to deploying existing technologies.

Federal Policy Challenges and Proposed Reforms. With Zika in the news, federal officials are debating funding legislation for vector control operations, but they have placed little focus on policies that limit available tools for vector control or that needlessly raise the costs of these programs. Congress can pass a massive spending bill, but the effectiveness of the programs they fund is greatly undermined by federal regulation.

Federal pesticide laws are a substantial problem because unscientific and excessively restrictive standards have produced bans and forced useful products off the market. Essentially, it has become too expensive for companies to invest in public health pesticides, and there are few left available for mosquito control. That means resistance issues are very difficult to manage and pesticides are less effective.

This problem began decades ago. In 1992, a National Academy of Sciences report warned: "A growing problem in controlling vector-borne diseases is the diminishing supply of effective pesticides." Because all pesticides must go through an excessively onerous registration process at the U.S. Environmental Protection Agency (EPA), "some manufacturers have chosen not to reregister their products because of the expenses of gathering safety data. Partly as a result, many effective pesticides over the past 40 years to control agricultural pests and vectors of human disease are no longer available."[16]

In 1996, Congress made the problem worse with the passage of the Food Quality Protection Act (FQPA), which tightened pesticide regulation when changes were not warranted to protect public health.[17] In fact, many lawmakers thought they were loosening standards when they voted to pass the law only to learn that it would eventually reduce the number of products available for agriculture and public health uses.[18] As a result of the FQPA, pesticide companies are abandoning products at an increasing rate because of costly regulations imposed by the EPA, and are introducing few new products to replace them. That means mosquito control officials are forced to use a handful products, which hinders efforts to control resistance.[19]

If federal lawmakers are truly interested in fighting Zika and other emerging vector-borne infections, they need to revisit the FQPA standard to eliminate the regulatory burdens associated with its excessively cautious approach. Ironically designed to protect public health, the Act's standards imperil public health and safety by eliminating potentially life-saving products based on unproven theoretical risks associated with trace chemicals.[20]

To add insult to injury, vector control has grown even more complicated and expensive because of red tape associated with the Clean Water Act (CWA). In 2009 a federal court ruled that the law applied to already legal products used for vector control. As a result, local vector control operations must get Clean Water Act permits before adding larvicides to standing water or spraying pesticides near waterways. These regulations require expensive and time-consuming bureaucratic paperwork and drain local government budgets. In addition, the CWA allows activists to bring citizen suits against local government for paperwork violations, holding up vector control operations and raising costs for no good reason. These products had already undergone EPA approval to ensure safe use and should be allowed as long as those applying the products follow labeling guidelines.[21]

There are some new technologies coming online that may help in the battle against vector-borne diseases. Yet as Hoover Institution scholar Henry I. Miller, M.D., has noted, such promising technologies are being undermined by misguided government regulations. For example, Food and Drug Administration (FDA) rules related to vaccines require excessive testing, which needlessly increases the cost and slows FDA approval.[22] Federal lawmakers should review and revise these vaccine approval procedures to allow greater innovation.

Similarly, genetically modified mosquitoes could play a role if regulators would allow it. The British company Oxitec explains how its mosquitoes can reduce populations of the *Aedes aegypti* mosquito, which carries both dengue and the Zika viruses:

> The Oxitec solution harnesses the natural instincts of male mosquitoes to find females in the wild. Oxitec has used genetic engineering to create "self-limiting" [i.e., sterile] male insects which seek out and mate with females. After an Oxitec male mosquito has successfully mated with a wild female, any offspring that result will not survive to adulthood, so the mosquito population declines. … By applying the Oxitec Control Programme to an area, the mosquito population in that area can be dramatically reduced or eliminated.[23]

And as Miller further explains: "Genetic engineering approaches are the kinds of breakthroughs that could spell the beginning of the end for malaria, dengue, Zika and other mosquito-borne diseases and relegate them largely to the history books, as medical science has done for smallpox and polio."[24] In fact, other technologies that use sterile insects have successfully been deployed to eradicate other nasty pests.

For example, one of the most touted successes involved eradication of screwworms, which lay eggs on livestock, pets, wildlife, and even humans (if they have no other option). Maggots, which later hatch, enter tissue through cuts or other openings and live inside the animal, consuming its flesh until the host either dies or until the worms are surgically removed. But these insects were eradicated from the United States by 1982 via the release of sterile male screwworms that researchers produced using radiation.[25] When these bred with females they produced no offspring and screwworm numbers declined. There had not been any cases of disease related to screwworms in the Americas since 1982, until recently when an infestation emerged in the Florida Keys. Hopefully, these will be eradicated soon with the help of such technologies.[26]

Oxitec mosquitos could produce similar results for the control of Zika-transmitting mosquitos, yet people will continue to get sick as officials delay implementation. According to Miller and his colleague John Cohrssen, FDA approval of these mosquitos has been dreadfully slow.[27] In fact, since a Dengue outbreak in 2011, public officials with the mosquito control district of Key Haven, in the Florida Keys, have been trying to gain FDA permission to release Oxitec mosquitos. Local environmental activists have added to the delays by spreading misinformation about the risks and referring to the genetically modified insects as "Frankenflies."[28] The FDA recently approved the trials, but the issue is first subject to a nonbinding referendum of the Key Haven residents in November. Because the referendum is nonbinding, the decision of whether to deploy the mosquitos is ultimately in the hands of the Key Haven mosquito control district's five-member control board.[29] Hopefully, the mosquito control district will deploy the Oxitec mosquitos, opening the door for other communities to follow suit.

Researchers with an international nonprofit program called Eliminate Dengue are developing yet another technology using laboratory-bred mosquitos that involves injecting mosquitoes with a bacterium called Wolbachia. This bacterium reduces the ability of mosquitoes to pass viruses to humans particularly dengue, Zika, chikungunya, and yellow fever. When female mosquitoes containing Wolbachia breed, they pass the bacteria on to their offspring. About 60 percent of insects naturally carry this bacterium, but it is not present in the species of mosquitoes that transmit dengue and Zika.[30] Once it is inserted and mosquitoes released, the bacteria can spread throughout mosquito populations, thereby reducing disease risks. Field trials in Australia look promising.[31] Even better news is that these researchers also say Wolbachia also has the potential to block transmission of malaria parasites, which are protozoan rather than viruses. Miller and Cohrssen says that EPA, which has the primary jurisdiction over this one, has been more reasonable.

Conclusion. Vector control officials need freedom to access and deploy existing technologies in situation-specific applications. This process will be greatly improved if lawmakers allow development of, and access to, new technologies that might take public health to the next level. Problems such as resistance to chemical controls are best addressed if new chemicals are developed and deployed. Accordingly, lawmakers in state legislatures and in Congress should not pick which products and strategies are used. Instead, they need to ensure that vector control experts have the freedom to do their jobs, and that there is a robust free market for the development of new pesticides and other vector control technologies.

Notes

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