

## Insight

# What Ebola Tells Us About Our Health Care System

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In the ongoing Ebola outbreak, a preventative measure taken in Liberia provides a rare insight into why the U.S. health care system is so costly and inflexible. Health care is one of the most regulated industries in the United States, and much of that regulation is not directed at ensuring the health of patients at all. Instead, it just entrenches incumbent organizations and existing ways of doing things – all the while decreasing efficiency, outlawing creativity, and increasing costs. The story of one company's response to Ebola in Africa – and how it compares to the response in America sheds light on the need for changes in health regulations that would allow for more flexibility, more rapid response, and lower costs, both in future health crises, and in reforming the U.S. health care system.

## FIRESTONE'S EBOLA RESPONSE

Firestone (the tire company) has a huge rubber farm and processing plant in Liberia that spans 120,000 acres and is home to 8,500 employees and over 71,000 dependents. On October 6, the Wall Street Journal, reported on measures taken at the Firestone rubber farm in Liberia to combat Ebola. On October 24, the CDC's *Mortality and Morbidity Weekly Report* featured further details.

This past March, Firestone's medical director was notified that an Ebola patient had "escaped" from a treatment center in northern Liberia and returned to the home where she lived with her Firestone-employed husband and their children. The next day, Firestone employees constructed an improvised 23-bed Ebola treatment unit—separate from the company's regular health clinic. They used cargo shipping containers and plastic wrap, and established a one-way "traffic" path for health care workers, with a place to don protective gear at the entrance and a place to remove it in a controlled manner at each exit. To protect health care workers, Firestone repurposed hazmat suits designed for cleaning up chemical spills, and respirators designed to protect against toxic volatile organic compounds. They also set up quarantine facilities in existing company housing near the new treatment facility.

Once the unit was set up, no health care workers there contracted Ebola, and no members of the Firestone community contracted it from an Ebola patient who was being quarantined or treated.

## US EBOLA TREATMENT CAPACITY

This simple story has several truly remarkable facts. First, the 23-bed improvised Ebola treatment facility contains *more Ebola treatment capacity than exists in the entire United States*. The US has two Ebola-ready isolation beds at Emory in Atlanta. The National Institutes of Health in Maryland has a Special Clinical Studies Unit which can hold two Ebola patients. The Nebraska Medical Center in Omaha has a 10-bed biocontainment unit, but because of the unique waste disposal requirements associated with Ebola, it can handle only two, or possibly three, Ebola cases at a time. St. Patrick Hospital in Missoula, Montana can take one, or possibly two,

more. This means that the US health system can properly treat at most *nine* Ebola patients at a time—less than half as many as Firestone's improvised facility in Liberia.

Why the difference? It's worth considering what would have to happen in order to set up a Firestone-like Ebola treatment unit in the US. In particular, consider what regulatory barriers would have to be surmounted to do so legally.

## **US REGULATORY HURDLES**

#### **Certificate of Need**

36 states plus DC have regulations that require a "Certificate of Need" to be issued before any hospital or hospital-like facility is constructed or expanded, or if any beds are converted from one type of unit to another. In addition, Title VI of the Affordable Care Act (ACA) prohibits certain types of hospitals from increasing the number of operating rooms, procedure rooms, or beds without permission from the federal government. The purpose of these laws, according to their advocates, is to prevent wasteful excess capacity. The effect, according to their detractors, is to limit competition and keep hospital revenues high. The details vary from state to state, but in general the minimum amount of time required by law is about six months, and the process normally takes at least 18 months. The 14 states that don't have "Certificate of Need" laws generally have other requirements that would impose some delays, albeit shorter ones. Firestone set up their facility in about a day, and admitted their first patient less than 48 hours after beginning construction.

#### **CLIA Certification**

In addition to bed approval, in order to conduct lab tests of any sort, the facility would have to obtain certification under the Clinical Laboratory Improvement Amendments (CLIA) from the Centers for Medicare and Medicaid Services. Otherwise, they would be limited to pre-packaged tests granted by CLIA waivers, in which case they would still need to obtain a "Certificate of Waiver" from CMS.

# **Facility Licensing**

There are also ownership rules to contend with. In many states, a "clinic" cannot be owned by anyone other than a licensed physician. Firestone, as a corporation, wouldn't qualify to be a certified "clinic". But since patients stay overnight, some states would apply hospital licensing rules, which are much more complicated—and the ACA prohibits new hospitals from being owned by physicians. It is unclear whether Firestone—as a company not in the hospital business—could operate a hospital on its own premises without establishing a separate hospital corporation as a subsidiary.

## **Equipment and Admittance Approval**

Given the types of chemicals involved in processing rubber, the industrial protective gear given to Firestone health care workers could probably withstand chemicals much more hazardous and corrosive than infected bodily fluids. However, they are not FDA-approved Class I, II, or III medical devices, and thus would not be legal as personal protective equipment (PPE) at a US health care facility even if they vastly exceed the standards

for those devices.

Further, used shipping containers supplemented with plastic wrap is not the easiest type of structure for which to get approval under the building codes and zoning requirements of most localities in the US. In addition to local building codes, a US facility would have to make sure its hallways were wide enough, and counters the right height, to comply with the Americans with Disabilities Act.

And finally, Firestone didn't have to wait to accept patients until it received approval from the Joint Commission (formerly known as the Joint Commission for Accreditation of Health Care Organizations).

### CONCLUSION

In short, the facility that Firestone put together on the fly in less than 48 hours would have taken 18 to 36 months, and a much larger amount of money, to set up in the United States—and the difference is due solely to various regulations in effect in the US.

This gives us a rare glimpse of the extent to which regulation makes health care both less flexible and more expensive than it has to be. Health care is one of the most regulated industries in the United States, and much of that regulation is not directed at ensuring the health of patients at all. Proponents of the ACA claimed it would "bend the cost curve downwards." In fact, it merely entrenched even further an unnecessarily inefficient and overly costly system—and did nothing to allow the sort of flexibility that would be necessary to deal with any type of public health crisis, let alone do so at a reasonable cost.