CENTER FOR JUSTICE & DEMOCRACY
CJ&D
at NEW YORK LAW SCHOOL

IMPACT

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...news, views and reviews from the Center for Justice & Democracy

CENTER FOR JUSTICE & DEMOCRACY **NEWS**

Dear Friends,

While traditional "tort reforms" like caps on damages are still a focus of Big Business and organized medicine, much of the discussion at both the federal and state levels has switched to proposals that would institute systems to keep victims completely out of court.

In the area of medical malpractice, for example, these proposals include: safe harbors for doctors who follow clinical guidelines; so-called "communication and resolution" systems that short-change patients; and health courts, allowing representatives of the health care industry to decide cases. These are all very dangerous ideas.

We are proud to say that CJ&D has more expertise on these issues than any other consumer group in the nation. We are regularly publishing new materials on this topic, most recently a letter to the editor in the *Wall Street Journal*.

CJ&D will be engaged in public education efforts throughout the year on proposals like these, including production of new materials, blogs and social media outreach. If you hear about these kinds of ideas circulating where you are, please let us know. We're glad to help.

Sincerely,

Joanne Doroshow
Executive Director

IN THIS ISSUE: INFECTIOUS DISEASES

EBOLA IN THE U.S.

In March 2014, international health agencies reported that West African Guinea's first outbreak of Ebola fever had killed at least 59 people and warned that the virus might be spreading into nearby countries. And spread it did, with Liberia and Sierra Leone adding their names to the roster of most severely affected countries. By August 2014, the World Health Organization declared the West Africa outbreak a "Public Health Emergency of International Concern," with 2,127 cases and 1,145 deaths reported but deemed a gross underestimate.

That same month, the United States flew its first known Ebola-infected patient – an American physician who contracted the disease while working in West Africa – back to a U.S. hospital for treatment. He walked out infection-free weeks later. Thomas Eric Duncan was not so lucky. In September 2014, the 42-year-old Liberian citizen came to America for the first time to visit family and friends. Days later, Duncan walked into Texas Health Presbyterian Hospital with a fever and abdominal pain, telling medical staff that he'd recently come from West Africa. Medical records show that Duncan's fever spiked to 103 degrees while in the emergency room, a fever flagged with an exclamation point in Presbyterian's record-keeping system.

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FOOD CAN MAKE YOU SICK

The Centers for Disease Control and Prevention (CDC) estimates that tainted food sickens 48 million Americans a year, sends nearly 128,000 of them to the hospital and leaves more than 3,000 dead. It is also estimated that foodborne diseases cause as much as $77 billion in health-related costs (*e.g.*, medical costs, diminished quality of life, lost productivity and lost-life expectancy) per year.

Salmonella, listeria and E. coli are among the foodborne pathogens linked to recent outbreaks. The CDC estimates that salmonella is responsible for one million illnesses in the U.S. each year, resulting in 19,000 hospitalizations and 380 deaths, and causes an estimated $3.7 billion in medical costs for Americans each year, according to the U.S. Department of Agriculture

Listeria is a less common but more serious infection that primarily affects people with vulnerable immune systems, such as seniors, pregnant women and newborns. As reported by the CDC in February 2015, listeria-tainted apples recently infected 35 people in 12 states, with all victims but one requiring hos-

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Despite an August Centers for Disease Control (CDC) warning that health-care providers should be on the look-out for patients who'd been in areas with "active" Ebola transmission and exhibited 101.5 degree-plus fevers as well as symptoms like abdominal pain, Duncan was sent home with antibiotics. Three days later, he returned to the hospital by ambulance and, on September 30, 2014, became the first patient diagnosed with Ebola in the United States after as many as 100 people had potentially come into contact with him. On October 8, 2014, Duncan became the first Ebola patient to die in the U.S.

Within days, Nina Pham, a nurse who took care of Duncan, tested positive for Ebola and became the first known person to contract the disease in the United States. In fact, the 26-year-old became internationally known thanks to information released by Presbyterian's parent company, Texas Health Resources (THR), as she remained hospitalized and battled the deadly disease. Pham ultimately survived and was declared Ebola-free on October 24, 2014, two weeks after her diagnosis.

Both Pham and Duncan's survivors turned to the civil courts for justice. Duncan's family filed a medical malpractice lawsuit against Presbyterian, THR and two physician groups, which was settled 35 days after his death. Under the agreement, Duncan's family received an undisclosed amount and THR pledged to set up a charitable foundation in his name. This settlement was fortunate given that Texas's "tort reform" laws make it extremely difficult for injured patients and their families to sue over medical errors, especially those that occur in the emergency room. As a November 12, 2014 *Associated Press* article explained, "Texas medical malpractice law places a $250,000 limit on noneconomic damages related to pain and suffering in almost all cases. It also gives extra protection to emergency room doctors and nurses. Instead of just proving that Duncan's

doctors were negligent in his care, Duncan's family would have to prove that any negligence was 'willful and wanton' – essentially, that doctors knew they were causing harm when they treated Duncan." Though THR was praised for quickly taking legal responsibility for Duncan's death, especially since Texas law may have immunized the hospital from suit, the company's motives may not be so altruistic. According to *AP,* weeks of bad PR stemming from Presbyterian's handling of Duncan's case severely affected THR's bottom line, with visits to Presbyterian's emergency room falling more than 50 percent during the first 20 days of October, and the hospital's overall patient census falling 21 percent.

Nina Pham's civil lawsuit was filed in March 2015. Among the more disturbing allegations in Pham's complaint: the hospital knew when Pham got sick that she didn't want her name made public but THR used her as a "public relations pawn"; THR never had Pham's permission to shoot or release a video of her isolated in the hospital, which was filmed on a GoPro camera under a physician's hood; and THR told the public Pham's condition had improved while hospital health workers held end-of-life discussions with her despite her inability to make decisions. Moreover, according to the complaint, THR's hospital had little regard for worker safety, with Pham never being trained to handle infectious diseases and only being given "Googled" Ebola information by her boss before meeting Duncan, forcing her to come up with her own protective gear protocols.

In announcing her suit, Pham said that she'd initially hoped THR would be "more open and honest about everything that happened at the hospital, and the things they didn't do that led to me getting infected with Ebola. But that didn't happen, and I felt I was left with no choice but to turn to the courts for help." She added, "I'm facing a

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EBOLA IN THE U.S. continued…

number of issues with regard to my health and my career, and the lawsuit provides a way to address them. But more importantly, it will help uncover the truth of what happened, and educate all healthcare providers and administrators about ways to be better prepared for the next public health emergency."

So far THR has tried its best to make sure this doesn't happen. The company argues that Pham's allegations of poor protection and training fall under workers' compensation claims, which, if allowed, would not only kill Pham's suit but also limit THR's legal and financial exposure. On April 20, a judge issued a restraining order to

prevent THR from seeking a worker's comp claim for Pham. Nearly a month later, the judge not only extended the restraining order to mid-July but also threatened THR and its insurance company with sanctions after learning that they might have intentionally withheld discovery documents damaging to THR. "We have been playing these games with THR since the filing of this lawsuit," Pham's lawyer told the *Dallas Morning News*. "We believed these documents existed all along. We've had to fight and claw and do everything within our power to uncover these documents so the truth can come out," she said. A civil jury trial would give Pham that opportunity.

FOOD CAN MAKE YOU SICK continued…

pitalization. Listeria contributed to at least three of seven deaths, 11 pregnancy-related illnesses and three cases of meningitis in children aged 5-15. More recently, Blue Bell Ice Cream has been linked to a total of three deaths and seven illnesses in 4 states.

Shiga toxin-producing strains of E. coli (STECs) are responsible for most food-related E. coli infections, usually being associated with ground or mechanically tenderized meats, sprouts and raw vegetables as well as unpasteurized juices, milk and cheese. According to the CDC, an estimated 265,000 STEC infections occur each year in the U.S. In July 2014, the California Department of Health reported that a 33-person, multi-state outbreak of foodborne E. coli in 2013 was connected to salad products sold at Trader Joe's and other retailers.

As for who's in charge of preventing foodborne infections, the "oversight system is a study in dysfunction," largely due to the "balkanized nature of safety inspections," reported the May 10, 2015 *New York Times*, with 15 federal agencies administering at least 30 laws related to food safety. The USDA Food Safety and Inspection Service (FSIS) has jurisdiction over meat, poultry and processed egg products and the U.S. Food and Drug Administration (FDA) has jurisdiction over everything else. "In theory, the line between these two should be simple," explained a February 2, 2015 *New Yorker* article. "In practice, that line is hopelessly blurred. Fish are the province of the F.D.A. – except catfish,

which falls under the F.S.I.S. Frozen cheese pizza is regulated by the F.D.A., but frozen pizza with slices of pepperoni is monitored by the F.S.I.S. Bagel dogs are F.D.A.; corn dogs, F.S.I.S. The skin of a link sausage is F.D.A., but the meat inside is F.S.I.S." Moreover, the fact that the FDA is woefully underfunded and understaffed makes it much more difficult for the agency to ensure the safety of nearly 80 percent of the nation's food supply that's under FDA jurisdiction. This absence of meaningful federal oversight has allowed growers and producers to hand over critical food inspection responsibilities to private auditing companies that have a financial incentive to issue favorable reports to ensure repeat business.

And when an outbreak happens, it's usually up to FSIS and the FDA to decide how to keep contaminated food off the market and hold companies accountable. Both agencies have the option to do nothing, carry out investigations, issue health alerts and shut down plants, yet only the FDA can force a company to recall foods tainted with pathogens, while neither agency can directly impose civil or criminal penalties.

Though civil lawsuits can fill the gap when regulatory agencies and food companies fail to keep the public safe, Congress still needs to take action to address systemic problems with the current U.S. food safety system. Increasing the FDA's budget so it can proactively respond to and prevent food contamination is one essential next step. Passing legislation that requires the USDA to recall any meat, poultry or egg products that contain life-threatening bacteria or viruses is another.

CONTAMINATED DRUGS AND MEDICAL DEVICES

Drugs and medical devices are supposed to preserve or improve our health. Yet when made negligently or recklessly or used by medical providers without regard to safety, such medical products can cause or transmit dangerous infections that are life-altering and sometimes lethal. Below are two recent examples.

Injectable Steroids

Over 750 patients were injured in 20 states, leaving 64 people dead, all due to fungus-tainted steroids made and sold by the New England Compounding Center (NECC). The Massachusetts pharmacy had been unlawfully manufacturing injectable steroids for the mass market, ignoring proper sterilization/decontamination procedures and shipping tens of thousands of vials to clinics and hospitals without adequate sterility testing.

A 2013 Congressional investigation concluded that the FDA had deliberately ignored "[t]en years of warning signs, alarm bells, and flashing red lights" from "patients, nurses, pharmacists, doctors, pain clinics, hospitals, drug companies, drug distributors and even confidential company informants" and allowed NECC to continue manufacturing contaminated products without consequence.

It took the NECC disaster for Congress to address gaps in federal oversight of compounding pharmacies that mass-produce custom drugs and supply them directly to hospitals and doctors. Unfortunately for patients, the result was weak 2013 legislation that lets large compounders decide whether they want to be subject to FDA rules on quality control and oversight. As reported by the *New York Times*, even the FDA "expressed disappointment that it fell short of giving the agency fuller regulatory power."

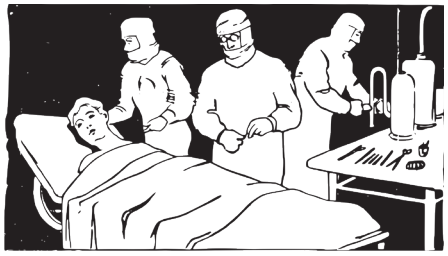
In December 2014, nearly two years after the fungal meningitis outbreak, federal prosecutors announced a 131-count criminal indictment – the largest U.S. criminal case ever brought over contaminated medicine – against 14 former NECC employees, including NECC's owner and a supervisory pharmacist who were charged with 25 acts of second-degree murder.

Unlike law enforcement, regulators and lawmakers, victims and their families didn't wait to take action, with an injured patient in Minnesota filing the first of thousands of lawsuits against NECC on October 12, 2012. Since then, NECC shut down, surrendered its licenses and declared bankruptcy, with the number of those seeking justice in the civil courts growing to 3,770 people nationwide. In May 2015, a federal judge approved a $200 million settlement plan that includes a "Tort Trust" to compensate victims who became ill or died from after being injected with contaminated NECC steroids.

Duodenoscopes

These flexible tubes – outfitted with advanced cameras, tiny lights and many other small working parts and used in over 600,000 procedures each year in the U.S. – are threaded down the throat and used to diagnose or treat gallstones, certain cancers and other digestive disorders, usually in patients' pancretic or bile ducts. According to the FDA, "If not thoroughly cleaned and disinfected, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient infection."

The recent rise in duodenoscope-related infections across the U.S. reveals a more frequent, lurking danger than the FDA's willing to admit. For example, in 2012, the University of Pittsburgh Medical



Center linked an 18-patient bacterial "superbug" outbreak to ineffective cleaning and disinfection guidelines from the duodenoscope manufacturer. In 2013, 39 patients at one Illinois hospital were infected with antibiotic-resistant E. coli on duodenoscopes despite their being properly disinfected to the manufacturer's specifications. At Seattle's Virginia Mason Medical Center, dirty duodenoscopes caused a drug-resistant bacterial outbreak that infected at least 32 patients, killing 11, between 2012 and 2014. In February 2015, UCLA Medical Center warned that nearly 180 patients might have been exposed to potentially deadly bacteria from contaminated duodenoscopes, bacteria that had already killed 2 patients. Since then, Cedars-Sinai Medical Center announced that four duodenoscope patients had tested positive for drug-resistant bacteria, with 67 additional patients possibly exposed, and Connecticut's Hartford Hospital said that 218 patients were exposed to E. coli from tainted duodenoscopes.

As this public health crisis continues to unfold, with Congress and safety advocates calling for answers and manufacturer Olympus subject to a U.S. Justice Department subpoena, victims and their families are pursuing accountability through the tort system. On February 23, 2015, the first lawsuit against Olympus was filed on behalf of an 18-year-old high school student, who was repeatedly exposed to a contaminated duodenoscope while a patient at UCLA. "The lawsuit is almost beside the point," Aaron Young's mother told the *Washington Post* on March 5. "We'd just like them to do something so that people are better informed. Nobody said Aaron could get something from these scopes that could kill him.... We just had no idea."