PUBLIC CITIZEN Health Letter

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An Ongoing Public Health Catastrophe: Public Citizen Continues Work on Fungal Meningitis Outbreak

In December 2012, *Health Letter* reported on the widespread outbreak of fungal meningitis that was linked to injections of contaminated steroid medication administered for back pain. The contaminated steroid had been produced by the New England Compounding Center (NECC), a company located in Framingham, Mass., that identified itself as a compounding pharmacy.

Drug compounding traditionally involves a local pharmacist combining, mixing or altering ingredients to create a unique, custom medication for an individual patient whose medical needs cannot be met by a standard, commercially available brand-name or generic drug manufactured by a drug company. Many companies, like NECC, have extended their operations well beyond traditional compounding and engaged in illegal drug manufacturing — the large-scale production and distribution of standardized formulations of multiple drugs that were not approved by the Food and Drug Administration (FDA) — under the guise of pharmacy compounding.

In the wake of the preventable public health disaster caused by contaminated drugs produced by NECC, Public Citizen has been highly critical of the FDA for failing to use the agency's existing legal authority to take aggressive enforcement action against companies like NECC — action that could have averted this disaster. This article provides an update on the scope of the fungal meningitis outbreak, the impact on affected patients and actions taken by the FDA against NECC.

The scope and course of the fungal infection outbreak

On Sept. 18, 2012, doctors at Vanderbilt University in Nashville, Tenn., diagnosed a rare case of life-threatening fungal meningitis in an otherwise healthy patient. The infection was caused by a type of mold called Aspergillus fumigatus, which the doctors quickly suspected was linked to a contaminated injection of steroid medication administered for back pain. Thus began one of the most serious infectious disease outbreaks in modern U.S. history due to contamination of a drug produced by a company identified as a compounding pharmacy.

Within a month of the diagnosis of the initial case, the fungal meningitis outbreak involved 137 cases in 10 states, including 12 deaths. By late September 2012, epidemiologists from the U.S. Centers for Disease Control and Prevention (CDC) linked the source of the outbreak to contaminated vials of a steroid, methylprednisolone acetate, produced by NECC. The CDC discovered that a total of approximately 17,500 vials from three contaminated lots of this drug had been shipped by NECC to 75 medical facilities in 23 states, where they were used to treat more than 13,400 patients with back or peripheral joint pain.

As of Aug. 5, 2013, 749 patients across 20 states had developed fungal infections after exposure to NECC's contaminated steroid drugs. Sixty-three of these patients have died, although the CDC noted that death may not have been attributed to fungal infection in all cases. Michigan and Tennessee had the highest number of cases, 264 and 153, respectively. Fortunately, since the early spring, the number of newly diagnosed fungal infections linked to the NECC-produced steroids has dramatically decreased, with only four new cases diagnosed between June 3 and Aug. 5.

As the disease outbreak evolved, it became clear that the types of infections linked to treatment with the contaminated steroids were not limited to meningitis. Other types of fungal infections that have occurred include localized infections (abscesses or pockets of infection) in the spine or soft tissues surrounding the spine (paraspinal tissues) and infections in peripheral joints (for example, the knee or shoulder joint). These more localized infections

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Normal Memory Loss and Dementia: How to Tell the Difference

If you are an older adult, memory problems are probably a regular occurrence in your life. Memory lapses, such as misplacing your keys, forgetting your medication or missing an important appointment, often become more common as you age. Yet such problems can be particularly distressing for elderly adults, because it can be difficult for them to tell the difference between normal memory lapses and the start of a more serious decline into dementia due to Alzheimer's disease or other causes. Dementia, defined as chronic impairment in thinking and social abilities severe enough to interfere with daily functioning, is a concern for many people as they grow older. About 1 in 5 people who live past 65 will develop dementia in their lifetimes. This risk goes up as people age: More than 1 in 4 people over 85 have dementia, and about 40 percent of those over 90 are estimated to have the condition.

In a small number of cases, dementia is reversible. In others, diagnosing the condition can be an important first step toward putting appropriate social and medical support in place that will provide for a life that is as comfortable and normal as possible as mental function declines.

Read on to learn two simple tests to distinguish between normal memory loss and dementia, and be prepared to talk to a doctor when you or someone you care about may be experiencing problems.

Identifying normal memory loss, mild cognitive impairment and dementia

It is a normal part of healthy aging to experience some difficulty with memory or reasoning, two types of cognitive function. Physicians have developed two medical terms to describe individuals whose cognitive functioning has declined to a point at which it can no longer be considered healthy. When a person has some level of cognitive impairment that can be detected using an assessment test, but that person is nevertheless generally still able to function as normal independently, he or she can be diagnosed with a condition known as "mild cognitive impairment." The second term, "dementia," is used when the person's thinking or behavior becomes so impaired that he or she is no longer able to carry out normal daily activities independently. Since it is not easy to pinpoint the precise line between normal aging and mild cognitive impairment, or between mild cognitive impairment and dementia, physicians often need to diagnose these conditions by offering assessment tests and talking to the patient and family members about concerns with the patient's thinking or behavior. Cognitive assessment tests measure impairment in several different areas: ability to recall new information (short-term memory), reasoning, visuospatial ability (the ability to draw or arrange objects), language and personality. Impairment in any of these areas can be enough to support a diagnosis of mild cognitive impairment, whereas a dementia diagnosis generally requires identifying impairment in two or more areas, where the impairment also interferes with the person's ability to function at work or in a social setting.

Not everyone with mild cognitive impairment will go on to develop dementia, and others will develop dementia only very slowly. Each year, about 10 to 15 percent of people with mild cognitive impairment develop dementia caused by Alzheimer's disease.

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Two simple screening tests used by physicians to detect risk for dementia are included in the text box at right. If you or a loved one may be at risk, you should seek a more thorough assessment from a trained physician. Doctors can combine mental assessments with blood tests and other laboratory evaluations to identify causes of mild cognitive impairment or dementia.

Dementia causes, risks and treatments

About 70 percent of dementia patients are diagnosed with Alzheimer's disease. Other causes of dementia include vascular dementia, caused by restricted blood flow to the brain from stroke or other conditions; Parkinson's disease; chronic alcoholism; the use of some prescription drugs; and frontal lobe dementia, which is caused by changes to the frontal lobes of the brain.

Some people who experience memory loss do not have dementia. People with depression often complain of memory loss and have difficulty concentrating. Delirium, brought on by a drug reaction or sudden medical condition, can also cause problems with thinking. Both of these potentially treatable conditions can be incorrectly diagnosed as dementia and can also occur simultaneously with dementia.

Dementia is sometimes treatable, but such cases are relatively rare: Only about 1.5 percent of cases of mild to moderate dementia are fully reversible. Certain symptoms help identify these rare cases so appropriate treatment steps can be taken. (See the text box at right).

Other cases of dementia are not treatable, but certain factors affect your risk of getting the disease. Having a close relative with Alzheimer's disease increases your risk of developing Alzheimer's dementia, as does carrying a specific gene associated with the disease, known as the APOE4 gene. People who complete high school or college are at lower risk for dementia than people with less education. People who live a heart-healthy lifestyle by controlling their blood pressure and eating a healthful diet low in saturated fats and rich in vegetables, beans, fruits, nuts, cereals, fish and olive oil may be less likely to develop the symptoms of Alzheimer's disease or vascular dementia.

Simple Tests to Screen for Dementia

Here are two simple tests commonly used by physicians to identify patients who may be in need of more thorough assessment to diagnose for dementia. You can ask your family doctor to administer these tests in the office, or try taking them yourself at home.

Test One: Ask the test-taker to name as many animals as possible in 60 seconds. People with a high school education and no impairment should easily be able to name at least 15 animals. However, those with very limited education (for example, those that did not attend middle school or high school) may only be able to name 9 or 12 animals.

Test Two: Ask the test-taker to say three unrelated words (example: chair, Seattle, apricot), draw a picture of a clock set to a particular time (example: ten minutes after 11 o'clock), and then try to repeat the same three words again. The person earns one point for each correct word remembered and two points if the clock drawing includes a circle with all of the correct numbers in the right order and hands pointing at approximately the right positions. If anything is out of place on the clock, it earns zero points. A score of 2 or below is a good indicator of dementia.

Remember: These tests are not the same thing as a medical diagnosis of dementia. If you or your loved one struggles to name 15 animals (or 9 for those with minimal education), or gets a score of 2 or below on the clock test, it's time to ask your family doctor for help getting a more thorough medical assessment.

Symptoms and Risk Factors for Treatable Dementia

Talk to your doctor if you have identified difficulties with thought, memory or behavior and have one of these symptoms or risk factors, which indicate a rare cause of dementia or mild cognitive impairment that may be treatable.

Symptom or Risk Factor	Potential Diagnosis
Numbness, tingling or weakness in the hands, arms, legs or feet; tongue soreness; weight loss	Vitamin B_{12} deficiency
Shuffling gait, urinary incontinence	Abnormal buildup of fluid in the brain
Use of drugs that affect the brain, including benzodiazepines and anticholinergics	Side effects from medication
Tiredness, sensitivity to cold, constipation, weight gain, hair loss	Hypothyroidism
Recent head injury, headache, seizures, paralysis on one side of the body, swelling behind the eye	Bleeding in the spaces around the brain
A history of alcoholism, abnormal eye movements, eyelid drooping or double vision, loss of muscle coordination	Wernicke-Korsakoff syndrome (Vitamin B_1 deficiency), sometimes due to alcoholism
History of high-risk sexual behavior or illicit drug use	Syphilis or HIV-associated dementia

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There also is a growing body of evidence that physical and intellectual activity may help delay the onset of dementia symptoms. In particular, one randomized controlled clinical trial recently showed that a six-month program of physical activity offered modest improvements in cognitive performance among elderly subjects who reported memory problems but did not have dementia. (See the text box at right.) Moreover, walking and other physical activity carry minimal risks, are widely available at low cost, and have an array of other physical and mental health benefits.

There also is some evidence that controlling hypertension through drugs or lifestyle changes can help prevent the onset of vascular dementia or Alzheimer's disease, though the evidence is limited that such treatment can reverse cognitive decline in patients already diagnosed with vascular dementia. Treating hypertension has many health benefits, and you should not wait for a dementia diagnosis to get your hypertension under control.

Unfortunately, for most people with dementia, there is no effective treatment available that will restore mental functioning. The FDA has approved several drugs to treat Alzheimer's disease, but Public Citizen's WorstPills.org website has categorized each of these therapies as Do Not Use, because none produce meaningful improvements in cognitive or other functions and all carry harmful side effects. Other forms of dementia, such as frontal lobe dementia, also have no known effective treatment. However, therapy or counseling may be helpful in finding strategies to cope with memory loss and other symptoms. Therapy also can help address depression, which is common among elderly people with mild cognitive impairment and dementia and can produce similar symptoms.

Even if dementia symptoms are not treatable, diagnosing and becoming aware of impairment early on can help, because it encourages families to plan for the future. Families may benefit from extra time to develop a plan for obtaining health care, keeping the person with dementia safe and handling financial issues. Families and individuals also can use the diagnosis as an opportunity to talk about important legal decisions while the affected family member is still capable of making choices for themselves, including formulating an advance directive for end-of-life decisions and selecting a person to exercise power of attorney for financial, health and personal care decision-making.

Advice for patients

It is normal to experience problems with memory and thinking as you age. The odds are good that these problems are not signs of early dementia. However, if you start to become concerned that a member of your family has reached a level of impairment that is not normal, particularly if it creates difficulties carrying out daily activities, it is time to talk to a doctor about assessing the person for dementia.

You also can test at home for impairments using one of the simple tests identified in the text box on page 2. If the score is low enough to indicate dementia, you should talk about setting up an appointment for a more thorough evaluation.

Tell the doctor if you or a loved one have observed any of the symptoms or risk factors described in the text box. Talking to a doctor about these symptoms as soon as possible will help detect treatable causes of cognitive impairment or dementia and minimize potential harm. ✦

Physical Activity May Improve Cognitive Function

In 2008, the *Journal of the American Medical Association* published a study showing that a six-month program of physical activity led to modest improvements in cognitive function for adults over age 50 who reported memory problems but did not meet criteria for dementia. The study randomized 170 participants to receive either standard healthy lifestyle advice alone or lifestyle advice plus a home exercise program that encouraged them to complete at least three 50-minute sessions of physical activity per week. Participants chose their own programs, with most selecting walking or other aerobic exercise. Some also did light strength training.

At the end of the program, participants in the physical activity program had improved 1.3 points (on a scale of 0 to 70) on the Alzheimer's Disease Assessment Scale—Cognitive Subscale (ADAS—Cog), a measure of cognitive performance. By contrast, subjects enrolled in an earlier clinical trial of donepezil (ARICEPT), a drug approved to treat Alzheimer's dementia, demonstrated an improvement of only 0.5 points on the same scale. Moreover, some of the cognitive benefits of the exercise program could still be seen a year after the program ended, whereas patients who took donepezil for six months had no significant benefits at one year after treatment ended. The benefits of physical activity were similar regardless of whether participants actually met objective criteria for cognitive impairment or simply believed they had memory problems even though their objective performance was normal.

The researchers who conducted the experiment are not certain why exercise improves mental function but believe it may help by assisting with blood flow to the brain or providing a mentally stimulating environment.

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have occurred right at the sites of injections of the contaminated steroids. Some patients have experienced more than one type of fungal infection, such as meningitis and a spinal or paraspinal infection. The table at right shows the number of patients who have experienced each type of infection. Seven patients suffered strokes presumed to have been caused by fungal infections following back injections with a contaminated steroid.

One intriguing observation is that the type of fungus found in the first patient, Aspergillus fumigatus, has not been detected in any subsequent patients during the outbreak. Instead, a different type of mold called Exserohilum rostratum has been the predominant type of fungus causing the infections, detected in 153 patients. This type of mold typically causes disease in plants but rarely in humans. In fact, the CDC reported that fungal meningitis due to Exserohilum had never before been seen. (Exserohilum is a type of black mold commonly found in the environment, on plant debris, in soil and in water.)

Twelve other types of mold have been detected in a small number of cases (ranging from one to eight patients for each type). The fact that so many different types of mold have been isolated from patients with infections linked to the contaminated steroids is indicative of the filthy conditions under which these drugs were produced, as well as the abject failure of NECC to follow the necessary procedures for preparing and testing sterile drugs.

The most successful, safest treatment for these rarely or never-before-seen fungal infections is long and difficult and has evolved since the outbreak began, when the exact type of fungus causing the infections in many patients was unknown. Patients diagnosed early in the outbreak were initially treated with high doses of a combination of two antifungal antibiotics, amphotericin B (given intravenously) and voriconazole (given intravenously or orally), both of which have serious toxic side effects, particularly at high doses. Later in the outbreak, as physicians gained more experience treating these infections, most patients were treated with voriconazole alone. Amphotericin B was reserved for the sickest patients or those who could not tolerate the unpleasant side effects of voriconazole. Common adverse reactions seen with voriconazole include visual hallucinations, vision disturbances, confusion, concentration problems, nausea, liver damage, rash, fatigue and hair loss.

The ideal duration of treatment for these unusual infections has not been established. Three months appears to be sufficient for patients who only have meningitis and at three months of therapy have no evidence of fungal infection on spinal tap tests (tests done on the fluid that surrounds the spinal cord and brain, which is obtained by inserting a needle between two vertebral bones in the lower back). For patients who have localized abscesses in the spine or paraspinal tissues, treatment appears to be needed for six months or longer, and surgery is often needed to remove pockets of infected tissue.

Case Counts by Infection Type for Fungal Infection Outbreak

Type of Fungal Infection	Number of Patients
Meningitis only	233
Meningitis + paraspinal/spinal infection	151
Paraspinal/spinal infection only	323
Peripheral joint infection only	33
Paraspinal/spinal infection + peripheral joint infection	2
Stroke, without meningitis being diagnosed	7
Total	749

The FDA inspection

Between Oct. 1 and Oct. 26, 2012, the FDA conducted an extensive inspection of the NECC facilities and records. Notably, the NECC facility in which the contaminated steroid drugs were made was located adjacent to a garbage and recycling facility. The preliminary findings of the FDA inspection, which were released to the public on Oct. 26, 2012, demonstrated a facility used to make sterile drugs on a large scale that generally had filthy conditions and failed to implement even the most basic standard procedures needed to safely produce such drugs.

Among the specific findings cited in the FDA's inspection report were the following:

- Approximately 100 vials of the same injectable steroids that caused the fungal infection outbreak contained greenish-black foreign material and a white filamentous material inside, indicative of gross contamination.
- NECC was unable to demonstrate during the inspection that the steam autoclave procedure that was used to sterilize injectable drug products made from nonsterile ingredients was capable of sterilizing those products.
- Multiple problems were identified regarding NECC's ability to maintain its clean room, an enclosed space designed to maintain a controlled environment with low levels of airborne dust and surface contamination, which could lead to contamination of drugs being produced in this setting.
- NECC's own environmental monitoring revealed bacteria and mold in multiple locations, including on surfaces in its clean rooms, between January and September 2012. However, the FDA investigators observed that no documented corrective actions were taken to address these findings.

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Force-Feeding Guantanamo Prisoners Draws Scrutiny from Medical Community

The latest hunger strike in the Guantanamo Bay prison facility is now in its seventh month, at its peak involving 106 of the 166 prisoners remaining at the prison. President Barack Obama, who faced criticism for failing to follow through on his campaign promise to close the facility, is now being criticized for his response to the hunger strike.

From the beginning, the military's policy has been to feed the hunger strikers against their will in an attempt to break the strike. This practice has drawn scrutiny from human rights advocates and, increasingly, from the medical and bioethicist community, which points out that force-feeding of hunger strikers defies long-established ethical protocols.

Strikers' predicament and motivations

The first detainees transported to Guantanamo in January 2002 were those taken prisoner during the initial invasion and occupation of Afghanistan. At its peak in June 2003, the prison held 680 prisoners. Col. Lawrence Wilkerson, chief of staff to former Secretary of State Colin Powell in the George W. Bush administration, claimed that the administration knew at the time that "the vast majority" of detainees at Guantanamo Bay were innocent. The military effectively acknowledged this by releasing or transferring most prisoners from the facility following unfavorable press and increasing opposition to the compound.

Today, 166 men remain imprisoned at the compound. More than half (86) of the remaining inmates — and some of the hunger strikers — have already been cleared for release, yet they remain in confinement. Though some have blamed Congress for restricting Obama's ability to transfer detainees, the legislation, passed in January 2011, only prohibits transfers to U.S. prisons, allowing Obama to repatriate detainees to their home countries if his administration certifies that the home country has met certain "security" guarantees. Obama refused to invoke this authority for more than 2½ years, until July 2013, when he repatriated two detainees to Algeria. Congress also cannot be blamed for a complete moratorium, instituted by Obama in January 2010 (and rescinded just this past May) on the repatriation of any Yemeni detainee (who represent the majority of detainees cleared for release) back to their home country.

Prisoners at the Guantanamo facility have initiated hunger strikes off and on since 2002, but previous strikes focused largely on the brutal conditions at the facility. The current strike, the largest and longest to date, has become a desperate attempt by the prisoners, who have lost hope of ever being released, to draw attention to their seemingly indefinite detention.

The force-feeding procedure

The standard operating procedure (SOP) governing the force-feeding at Guantanamo was revealed in a leaked document entitled "Medical Management of Detainees on Hunger Strike" written by the Joint Task Force's Joint Medical Group at the facility.

According to the SOP, the first action required of military physicians responding to a confirmed hunger striker is to elicit an oral statement from the detainee that he "fully understands" the health risks, including permanent impairment or death that could result from the strike (indicating that all Guantanamo hunger strikers recognize and accept the implications of their actions).

The military physician is instructed to initiate the forcible feedings on day 21 of the hunger strike or once certain visible health effects begin to manifest. Detainees are first strapped to a bed with the head elevated to help prevent inadvertent swallowing of the food contents into the lungs. A hollow rubber tube is then inserted through the nostrils and down the throat until it reaches the stomach. This is the most painful and distressing part of the procedure. Once the tube is confirmed in place in the stomach, a liquid nutrition supplement is pumped into the tube. Inmates can either be fed continuously or intermittently.

As any health care professional knows, this nasogastric feeding procedure is unpleasant enough for consenting patients for whom a medical benefit is desired. One can imagine the experience for inmates who undergo the procedure forcibly, on a daily basis, with no end in sight.

Because the feedings at Guantanamo are shielded from public view, hip hop artist Yasiin Bey (better known as Mos Def) volunteered to submit to a recorded demonstration of the procedure (which followed the Pentagon's SOP used on detainees) organized by the British human rights organization Reprieve. In the four-minute video, Bey is strapped down while a tube is inserted into his nostrils and down his throat. Though it is only a demonstration, Bey can tolerate the procedure for no more than a minute before tearfully pleading with the staff to stop.

Consensus on ethical guidelines

The World Medical Association (WMA), the leading international physician organization tasked with formulating medical ethics standards, states unequivocally that "forcible feeding is never ethically acceptable. Even if intended to benefit, feeding accompanied by threats, coercion, force or use of physical restraints is a form of inhuman and degrading treatment."

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The WMA bases its conclusion on the core ethical principles of autonomy and informed consent. A physician is only allowed to administer medical care within the context of a consensually established doctor-patient relationship. Not all hunger strikers request a physician's assistance, and it is increasingly clear that Guantanamo detainees do not want military physicians treating them. In May 2013, 13 detainees sent an open letter to their military doctors pleading for independent physicians to take over their care. In response, 153 physicians penned an open letter in the *Lancet* medical journal to President Obama, urging him to allow them to visit with and care for the detainees, in accordance with international ethical guidelines. The letters have so far been ignored, and independent physicians are still barred from the facility.

Once a striker consents to being under the care of a physician, the WMA's guidelines require the physician to first assess the striker's motivations and competence to ensure that he or she came to the decision autonomously, without outside coercion, and is fully aware of the consequences of his or her actions. The physician must then ensure that the striker recognizes and accepts the health implications of the strike. Finally, the physician assesses the wishes of the striker for medical treatment, including artificial feeding. The physician must conform to the prisoner's wishes, including a refusal for life-sustaining measures.

Although the WMA acknowledges that the natural inclination of physicians is toward preserving the health and well-being of their patients (the ethical principle known as beneficence), the association stresses that physicians' overarching obligation is to respect patients' autonomy, up to and including life-and-death decisions. "It is ethical to allow a determined hunger striker to die in dignity rather than submit that person to repeated interventions against his or her will," the WMA concludes.

The American Medical Association (AMA) endorsed the WMA's stance in an April 2013 letter to Secretary of Defense Chuck Hagel, imploring him to give "… prompt and thorough attention …" to the matter and reiterating its own position that "… the forced feeding of detainees violates core ethical values of the medical profession."

Two opposing perspectives on the force-feeding of Guantanamo detainees were published in the July 11, 2013, issue of the *New England Journal of Medicine (NEJM)*. On one side, prominent bioethicist George Annas and colleagues alluded to the consensus in the medical and bioethicist establishment against the practice: "That force-feeding of mentally competent hunger strikers violates basic medical ethics principles is not in serious dispute." Annas and colleagues went on to observe that, despite this consensus, few physicians were voicing their opposition to what he termed the "aggravated assault[s]" taking place at Guantanamo. (In a 2006 *NEJM* opinion piece, Annas also highlighted the hypocritical silence of leading bioethicists on the U.S. President's Council for Bioethics, who in 2003 labeled the Soviet Union's force-feeding of its own political prisoners in the 1970s as "torture" while remaining silent when the practice was replicated two years later during the first Guantanamo hunger strike. Annas stated, "It is easy to condemn the brutal actions of Soviet-era jailers against political dissidents. It is much more difficult to address the acts of our own country, especially acts, different only in the degree, that have been used by U.S. military physicians against hunger strikers at Guantanamo Bay, Cuba.")

The opposing viewpoint published in the 2013 *NEJM* issue was voiced by political scientist Michael Gross. Gross argued that "autonomy is not sacrosanct" and that the sanctity of the prisoner's life and military priorities could override this most fundamental ethical principle. He concluded his piece by reminding medical professionals that they, like other citizens in what he called a "thriving democracy," must "simultaneously sustain the efforts of war and contain them." It is unclear why Gross conveniently attributed to physicians the responsibility to "sustain the efforts of war" rather than the notion that the primary duty of medical professionals is to their patients.

No legal recourse

U.S. courts have largely allowed the force-feeding of hunger strikers in U.S. prisons. Though at least one state court has ruled that certain competent detainees have a right to refuse life-sustaining medical treatment where there is no evidence that treatment will pose a threat to institutional security or public safety, courts have nevertheless consistently ruled in favor of prison authorities' right to force-feed hunger strikers to preserve "order" and "security" within the prison.

However, even if federal law were more favorable to hunger strikers' arguments, U.S. law, in many cases, cannot be applied to the Guantanamo prison facility, which was built in Cuba precisely to avoid legal scrutiny. Though the Supreme Court ruled in 2004 that U.S. courts had jurisdiction over the Guantanamo Bay prison, the ruling focused on detainees' right to appeal the legality of their detention, not their treatment while in detention. In 2006, Congress heavily restricted legal oversight of detainee treatment through the 2006 Military Commissions Act, which forbids any federal court, justice or judge "to hear or consider any other action against the United States or its agents relating to any aspect of the detention, transfer, treatment, trial or conditions of confinement" of aliens detained as enemy combatants.

Two federal court rulings in July 2013 reiterated this point when refusing to consider detainees' pleas for legal protections against force-feeding, even though one judge, Gladys Kessler, deemed the practice "painful, humiliating, and degrading." In Judge Kessler's case, the petitioner had been held for 11 years without charge and was one of the 86 prisoners already cleared for

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HRG Works for You!

Our latest work involves flawed FDA risk-mitigation policy, compounding pharmacy legislation, and two dangerous drugs

The work of Public Citizen's Health Research Group (HRG) doesn't end with its *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses our own research, current academic research, government data and information from whistle-blowers to advocate for consumers by:

- petitioning the government to remove unsafe drugs or medical devices from the market, and to require warnings of dangerous side effects on other drugs;
- testifying before government committees and arguing against approval of unsafe or ineffective drugs and medical devices;
- writing letters to government agencies about the adverse effects of drugs and medical devices; and
- urging Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest research-based consumer advocacy includes:

- **Public Citizen Opposes Approval of Drug with Liver Toxicity Risks at FDA Advisory Committee Meeting — 8/5/2013 —** In testimony before the Food and Drug Administration (FDA), Public Citizen spoke against approval of the drug tolvaptan for use in polycystic kidney disease, citing that it presents liver toxicity risks and that it does not meet essential elements of efficacy needed for drug approval.
- **Public Citizen Criticizes Dangerous, Flawed FDA Risk-Mitigation Program, Citing Examples of Five Drugs — 7/26/2013 —** In testimony before the FDA, Public Citizen criticized the agency's Risk Evaluation and Mitigation Strategies (REMS) program, citing several areas of failure of the program and noting five drugs that exemplify these failures.
- **Public Citizen Comments Regarding Pending Compounding Pharmacy Legislation — 7/15/2013 —** Public Citizen expresses our grave concerns with the three pending pieces of national legislation on pharmacy compounding. There may be significant differences between these three proposals, but all of them put patients at risk by permitting compounding pharmacies to engage in drug manufacturing activity without seeking a new drug approval from the FDA or complying with other important federal drug requirements.
- **Testimony to the FDA Drug Safety and Risk Management Advisory Committee on the Restrictions on the Use of Lotronex — 7/10/13 —** Public Citizen recommends that restrictions on the drug alosetron (brand name: Lotronex) be tightened, rather than loosened, due to its high risk of life-threatening adverse reactions compared with its marginal benefits.

Visit www.citizen.org/hrgpublications to read full reports and testimonies as HRG fights for government and industry accountability in the interest of the public's health.

Product Recalls

June 26, 2013 – July 30, 2013

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements (www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Estarylla (Norgestimate and Ethinyl Estradiol) Tablets, 0.25mg/0.035mg, 3 x 28 tablets per carton. Volume of product in commerce: 10,848 cartons. Lot #: LF01213A, expiration date 02/2014. Contraceptive tablets out of sequence: A placebo tablet was found in a row of active tablets. Sandoz Incorporated.

Nimodipine Capsules, 30 mg. Volume of product in commerce: 46,387 cartons. Multiple lots, multiple expiration dates. Contact your pharmacist. Crystallization: crystallized nimodipine. Sun Pharmaceutical Industries Inc.

Pure-Aid Allergy Relief, diphenhydramine HCL caplets, 25 mg, 20 caplets. Volume of product in commerce: 24,048 cartons. Lot #s: 6781202 and 6781302, expiration dates not specified. Labeling: Not elsewhere classified; foil label on immediate blister pack indicates active ingredient as chlorpheniramine rather than diphenhydramine. Kareway Product Inc.

Quetiapine Fumarate Tablets, 25 mg, 100-tablet blister card. Volume of product in commerce: 19,060 blister cards. Lot #: 122600, expiration date 03/2014. Failed dissolution test requirements: During analysis of long-term stability studies at three months, an out-of-specification (OOS) was reported. American Health Packaging.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Autumn Run Girls Gemma II Boots. An exposed staple in the sole of the boot presents a laceration hazard to the consumer. Renaissance Imports at (877) 632-2021 or www.renimp.com.

Baby Einstein Musical Motion Activity Jumpers. The "sun" toy attachment on the activity jumper can rebound with force and injure the infant, posing an impact hazard. Kids II at (877) 325-7056 or www.kidsii.com.

Boy's Long-Sleeve Hooded Jackets. The recalled jackets have drawstrings with toggles inside the bottom hem and neck area, posing a strangulation hazard to children. Mecca 5 Star at (880) 229-6833 or e-mail dsinger@5-starapparel.com.

Decorative Lamps. The lamps have exposed wiring at the base. This poses shock and fire hazards to consumers. Angel's Touch Collections at (877) 474-2133 or www.angeltouchcollections.com.

Electric Smokehouse Smokers. The wood chip tray can fail to slide securely into the smoker, causing the wood to combust and the smoker's cabinet door to blow open, posing a fire hazard. Masterbuilt Manufacturing at (800) 489-1581 or www.masterbuilt.com.

Hollis DG03 Dive Computers. The dive computer, when used with an optional integrated transmitter, can malfunction and display an incorrect tank pressure reading to the diver. A diver could unknowingly deplete their air supply based on the reading, resulting in drowning. Hollis toll-free at (888) 383-3483 or www.hollisgear.com.

Infants' First Impressions Varsity Jackets. The snaps on the jackets can come off, posing a choking hazard. Macy's at (888) 257-5949 or www.macys.com.

Johnny G. Krankcycle® by Matrix. The seat can unexpectedly detach from the Krankcycle's frame during use, posing a fall hazard to users. Johnson Health Tech North America at (866) 218-3674 or www.matrixfitness.com.

CONSUMER PRODUCTS (CONTINUED)

Kenmore Dehumidifiers. The dehumidifiers can overheat, smoke, melt and catch on fire, posing fire and burn hazards to consumers. LG Recall Fulfillment Center at (855) 400-4641 or www.kenmoredehumidifierrecall.com.

Loose Votive Candles. The candles can burn with a high flame, posing a fire and burn hazard. Swan Creek Candle Co. at (888) 804-8492 or www.swancreeekcandle.com.

Outdoor Solutions Hammock with Sunshade. The seam in the lounge of the hammock can open and rip, posing a fall hazard. H-E-B at (800) 432-3113 or www.heb.com.

Portable Generators. The fuel tank can leak, posing a fire or burn hazard. Robin America Inc. at (866) 664-1363 or www.subarupower.com.

Remote-Controlled 3-Channel Helicopters. The rechargeable battery inside the helicopters can overheat, posing fire and burn hazards to consumers or nearby items. Toys R Us at (800) 869-7787 or www.toysrus.com.

Rockland Furniture Round Cribs. The crib's drop-side rails can malfunction, detach or otherwise fail. When this happens, the drop-side rail can fall out of position and create a space where an infant or toddler can become wedged or entrapped, posing a risk of strangulation or suffocation. A child can also fall out of the crib. In addition, drop-side related incidents can also occur due to incorrect assembly and with age-related wear and tear. Rockland Furniture at (877) 967-5770 or www.rocklandimmobilizationkit.com.

Soleil Portable Fan Heaters. The portable fans' plastic housing can melt, deform and catch fire during use, posing a fire hazard. Home Depot at (877) 527-0313 or www.homedepot.com.

Tern Folding Bicycles. The bike's frame can crack at the hinge on the top tube, posing a fall hazard. Stile Products at (888) 570-8376 or www.ternbicycles.com.

Thermobaby Aquababy Bath Ring Seats. The bath seats fail to meet federal safety standards, including the requirement for stability. Specifically, the bath seats can tip over, posing a risk of drowning to babies. SCS Direct Inc. at (888) 749-1387 or www.SCSdirectinc.com.

UCO Arka LED Lanterns. The lantern's wall charger plug can fail during normal use, posing a fire hazard. Industrial Revolution at (888) 297-6062 or www.industrialrev.com.

Viking Built-In Refrigerators with Bottom Freezers. The refrigerator's doors can detach, posing an injury hazard to consumers. Viking at (877) 546-0136 or www.vikingrange.com.

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Given the FDA's inspection findings, the widespread outbreak of fungal meningitis and other infections caused by the NECC steroid drugs in retrospect comes as no surprise.

As we noted in the December 2012 issue of *Health Letter*, one of the more disturbing aspects of this story is the fact that several years before the outbreak, NECC had been warned by the FDA. On Dec. 4, 2006, the FDA cited the company for multiple violations of federal drug laws and other FDA regulations related to the large-scale production of at least four different drugs. These violations were identified during an FDA inspection of NECC conducted between September 2004 and January 2005. Among the violations was the failure of NECC to obtain FDA approval for new drugs. Had the FDA shown due diligence and conducted a follow-up inspection before, rather than after, the fungal meningitis outbreak began, the problems related to the NECC's production of sterile drugs likely would have been detected sooner, and the agency could have taken action to help prevent the current tragedy.

Unresolved aftermath

For many affected patients and their families, the fungal disease outbreak has caused great suffering and permanently altered, if not ended, their lives.

In the wake of the fungal disease outbreak, numerous lawsuits have been filed against NECC and its owners in federal and state courts around the country. However, because of the number of deaths and injuries and the fact that NECC has filed for bankruptcy and has limited assets, lawyers representing patients injured or killed by the contaminated steroids doubt that they will be able to recover just compensation from NECC, its owners or any liability insurers of the company. Other lawsuits have been brought against clinics and medical centers that bought and administered the contaminated steroid drugs to patients. These lawsuits undoubtedly will take years to be resolved.

In addition to the extensive civil litigation, the FDA's investigation into NECC is ongoing, and federal criminal charges potentially could be filed against the company and its owners in the future. Some states also may undertake criminal probes into the outbreak. For example, in March, Bill Schuette, the attorney general from Michigan — the state with the most cases of fungal infections tied to the outbreak — called for a criminal investigation by a state grand jury into the conduct of NECC related to the production and distribution of the contaminated drugs. In discussing the outbreak, Schuette said that "hundreds of Michigan citizens

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release. Kessler conceded the government's position that the court had no authority over the strikers but reminded the government that "there is an individual who does have the authority to address the issue," namely Obama.

Humanitarian smokescreens and public relations realities

The Obama administration has framed its choice to force-feed as a humanitarian gesture rather than strike-breaking. Shortly after the start of the most recent Guantanamo hunger strike, Obama claimed his administration was force-feeding detainees out of concern for their well-being, stating: "I don't want these individuals to die." Military officials have since insisted that inmates' safety and well-being is the sole motivation for the force-feeding policy, claiming an "ethical responsibility ... to assure the health and well-being of detainees." In its press releases, the military makes no mention of the following instructions, buried in the leaked SOP, to military physicians managing the hunger strike: "In event of a mass hunger strike, isolating hunger striking patients from each other is vital to prevent them from achieving solidarity." How this contributes to their "health and well-being" is not explained.

Official platitudes aside, a look at international precedents to the Guantanamo strike suggests that public relations concerns are the principal driver of the push to violently break the hunger strike. "It's a little bit of bad press if you force-feed inmates," explained bioethicist Dr. Jacob Appel in a recent interview with the nonprofit investigative journalism organization ProPublica. "It's a lot of bad press if you have a lot of protesting inmates and one of them dies."

The fate of Irish Nationalists detained by the British military during the Nationalist uprising in Northern Ireland in the 1970s and 1980s illustrates, perhaps more than any other event, why prison authorities worldwide prefer live, striking prisoners to dead ones. Beginning in 1976, Nationalist prisoners embarked on a series of hunger strikes and other political actions to protest a British decision to rescind detainees' status as political prisoners, labeling them instead as criminals and removing many of the limited privileges they had before, such as wearing their own clothing (as opposed to prison uniforms) and interacting freely with fellow prisoners.

In March 1981, the prisoners, led by Bobby Sands, embarked on what was to become their longest and deadliest strike in pursuit of political status. The strikers' determination to die if necessary led to international attention, with striking inmates becoming revered figures among Nationalists in Northern Ireland and around the world. Bobby Sands was elected to the British parliament while on hunger strike, and an estimated 100,000 people attended his funeral after his death 66 days into the strike. Nine more Nationalist prisoners would starve to death before the strike was called off in response to British concessions on some of the strikers' demands.

The Obama administration undoubtedly sees the outcome of the 1981 Northern Ireland hunger strike as a cautionary tale. The Nationalist prisoner deaths, resulting from British Prime Minister Margaret Thatcher's initial refusal to negotiate, made the strike a public relations debacle for the British government. Obama is desperate to avoid a similar scenario at Guantanamo. "You hear American officials say again and again, 'we don't want another Bobby Sands,'" noted George Annas in a recent interview with the *Christian Science Monitor*. And so the feedings continue. ✦

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and their families have endured terrible pain and deaths of loved ones suffering from illnesses caused by these tainted steroid injections. This investigation is necessary to uncover the truth as to how this unspeakable tragedy happened and to restore public faith in our healthcare system."

In the aftermath of the outbreak, Public Citizen urged the FDA to conduct inspections and to take aggressive enforcement action against other companies that, like NECC, appear to be engaged in illegal drug manufacturing under the guise of pharmacy compounding. The FDA began to take such action, inspecting more than 50 drug compounding facilities between December 2012 and June 2013. In nearly all cases, the FDA's reports of these inspections revealed significant problems related to the production of sterile drugs.

The U.S. Congress also has been debating several legislative proposals purportedly intended to prevent another similar disaster from occurring. Public Citizen has strongly opposed many of these proposals because they would weaken U.S. drug safety by exempting companies like NECC from the critically important legal requirements intended to ensure the safety and quality of all manufactured drugs that have been in place for more than half a century.

In future issues of *Health Letter*, we will discuss the implications and outcomes of these ongoing regulatory and legislative responses to the NECC-caused tragedy. ✦

PUBLICCITIZEN Health Letter

Outrage of the Month: Exploiting The Desire for Younger-Looking Skin

As we age, ideally we add the wisdom that comes only with living longer. But our bodies also inevitably age, most notably in the form of facial wrinkles that many people want to reduce — even erase — in order to appear younger to themselves and others.

Much has been written about the growing use of cosmetic Botox and collagen facial injections to address the signs of aging. Now ABC News has reviewed three unusual and outrageous treatments commercialized in this country.

The Geisha Facial: This treatment purports to boost facial complexion using a combination of steam treatment, aroma therapy and a paste made from powdered nightingale feces.

The Vampire Facelift: Blood is drawn from the patient, treated and then injected into the face to smooth out undesired wrinkles.

Face Slapping: Everyone knows that when we get injured, there is often accompanying swelling. ABC News describes this treatment as a process in which a "masseuse slaps the age right off her customers' faces."

Although none of these treatments are even semi-permanent, they all are expensive and raise serious questions about some people's unwillingness to age gracefully. While some aspects of aging can be dealt with through adequate physical and mental exercise and a healthy diet, the accompanying wrinkles had best be left alone — at least not slapped, injected with blood or other chemicals, or rubbed with animal feces. Increasingly, when we see people whose faces do not "look their age," the reason is that we are not really seeing their own faces.

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