



# Fungal Meningitis Outbreak Highlights the Dangers of Compounding Pharmacies

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. A culture of the patient’s cerebral spinal fluid revealed the cause of the infection: a type of mold called *Aspergillus*. The doctors quickly suspected that the source of the mold was an 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 compounding pharmacy.

Within two weeks, 13 additional patients — 12 in Tennessee and one in North Carolina — were found to have contracted fungal meningitis after receiving steroid injections for back pain. 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 the New England Compounding Center (NECC), a compounding pharmacy located in Framingham, Mass.

The outbreak represents an ongoing public health catastrophe: By Nov. 19, at least 490 people were affected (478 with meningitis and 12 with infected joints) across 19 states, and 34 have died. What is particularly tragic for those sickened or killed by the tainted drug, as well as their loved ones, is that this situation was completely avoidable.

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### What is drug compounding?

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. The preparation of such individually tailored drugs requires a prescription from a licensed health care provider.

Prior to the early 1900s, essentially all drugs in the U.S. were compounded for individual patients by pharmacists or physicians. After more than 100 patients were killed in 1937 by an antibiotic solution of sulfanilamide containing the highly toxic solvent diethylene glycol, Congress passed the Food, Drug and Cosmetic Act (FDCA) requiring drug companies to conduct tests to ensure a drug’s safety before it could be used in patients. The FDCA was amended in 1962 to require companies to show that new drugs were both safe and effective. With passage of the FDCA and the subsequent rapid expansion of the commercial drug manufacturing industry, use of compounded drugs greatly diminished.

Though the Food and Drug Administration (FDA), the agency responsible for enforcing the FDCA, has long considered the compounding of drugs

to be subject to FDA regulations, the agency has recognized both the useful health care role of drugs compounded for certain individual patients and the infeasibility of mandating that such traditional drug compounding comply with the same regulations imposed on drug companies. Therefore, it has used “enforcement discretion” to allow these companies to produce drugs without complying with FDA regulations, generally deferring regulatory oversight to state pharmacy boards.

Over the past two decades, many compounding pharmacies have expanded their reach by engaging in large-scale production of drugs, moving from the narrow role traditionally filled by such pharmacies into a realm clearly involving both drug manufacturing and the distribution of standardized

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formulations of drugs. In many cases, the drugs have been sold in multiple states, thus involving interstate commerce.

In the case of NECC, the company held pharmacy licenses in all 50 states and has produced and sold across the country thousands of different drugs.

**Compounded drugs produced under less stringent safety standards**

All drugs marketed in the U.S. are subject to multiple FDA regulatory requirements intended to ensure patient safety, including the following:

- *FDA review and approval.* Prior to marketing a drug, a drug manufacturer must obtain approval by the FDA of a new drug application. The application must provide evidence supporting the safety, efficacy and quality of the drug.
- *Good manufacturing practice (GMP).* Once approved, the drug must be manufactured in accordance with GMP regulations. These regulations are intended to ensure the quality and purity of the final finished product.
- *Labeling requirements.* Each drug approved by the FDA must include appropriate labeling that describes the drug's indications (the diseases and conditions for which the drug is approved), known side effects, warning about any potential serious adverse events, contraindications (circumstances in which the drug should not be used because it is too dangerous) and instructions for how to use the drug safely.

These regulatory requirements are intended to prevent exactly the type of public health disaster that is now unfolding as a result of fungal contamination in the injectable steroid medication produced by NECC. Indeed, the FDA has repeatedly asserted over the past two decades that compounding

pharmacies that engage in large-scale production and distribution of standardized versions of compounded drugs, such as NECC, are subject to the above regulatory requirements. However, most such companies have disregarded these requirements, placing huge numbers of patients at great risk.

**Previous noncompliance of NECC**

One of the many disturbing facts about the ongoing fungal meningitis scandal is that NECC previously had similar problems with contaminated injectable drugs.

In March 2002, the FDA received reports of two patients suffering adverse events after being treated with an injectable steroid, betamethasone. A subsequent inspection by FDA investigators and state regulators, one month later, identified concerns regarding the sterility of the betamethasone produced by NECC.

In October 2002, FDA investigators, along with state regulators, initiated yet another inspection of the NECC facility after the FDA received reports of three adverse events, including two cases of meningitis, associated with use of the injectable steroid methylprednisolone acetate — the same drug linked to the current fungal meningitis outbreak — that had been produced by the company. Subsequent tests of samples of the drug revealed bacterial contamination.

Most recently, on Dec. 4, 2006, the FDA cited the company for multiple violations of the FDCA related to the large-scale production of four different drugs.

The violations cited in the warning letter were based on a joint inspection of NECC by investigators from the FDA and inspectors from the Massachusetts Board of Registration in Pharmacy that took place over a four-month period between September 2004 and January 2005.

The FDA's letter explicitly noted that the agency had directed its

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“enforcement resources against [compounding pharmacies] whose activities raise the kinds of concern normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA.” The letter proceeded to cite NECC for numerous violations of the FDCA regarding the production of four different drugs, including a high-strength topical anesthetic cream and a drug intended for injection into the eye.

For all four of these drugs, the FDA found that NECC had violated the FDCA by not obtaining FDA approval. Furthermore, the agency declared these drugs misbranded because their labeling failed to include adequate directions for safe use and, in the case of the topical anesthetic cream, was false and misleading because it did not disclose the serious adverse events, including death, that could result from use of the product.

On the same day the FDA sent its Dec. 4, 2006, warning letter to NECC, it sent very similar warning letters to four other compounding pharmacies that were violating the requirements of the FDCA by producing and distributing standardized versions of topical anesthetic creams similar to the one produced by NECC. The agency issued a press release, “FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams,” stating that “firms that do not resolve violations in FDA warning letters risk enforcement such as injunctions against continuing violations and seizure of illegal products.”

Clearly, the FDA was attempting to send a broader warning targeting the entire compounding pharmacy community at large: Compounding pharmacies that behave like drug manufacturers (by engaging in large-scale manufacturing and distribution of standardized versions of drugs) must comply with all regulatory requirements related to the approval and manufacture of drugs or face enforcement action by the agency.

Following its 2006 warning letter to NECC, the FDA dropped the ball and failed to take the actions necessary to ensure that NECC did not continue to engage in large-scale drug production activities that violated both the FDCA and related FDA regulations. For whatever reason, whether inattentiveness or lack of resources, the FDA did not in this case aggressively enforce the regulations related to large-scale drug manufacturing and interstate commerce, thus allowing the company to continue wide-scale manufacturing and interstate distribution of many injectable medications, including steroids.

The injectable steroid medication produced by NECC was never approved by the FDA and was not manufactured in accordance with the rigorous manufacturing standards designed to ensure that drugs are uncontaminated by bacteria or fungi before being sold and distributed. As a result, as many as 14,000 patients in 23 states were exposed to potentially contaminated steroids and will need to be monitored for several months for signs of fungal meningitis or other infections.

The contaminated steroid injections, along with all other injectable products distributed by NECC, have now been recalled. Hospitals and physicians who administered shots linked to the outbreak have been instructed to contact patients who could have received contaminated injections as early as May 21, 2012. By mid-October, most patients had been contacted.

## A decade of other alarms

While the current infectious disease outbreak linked to a compounding pharmacy may be unique in terms of scope, similar troubling outbreaks linked to other compounding pharmacies have occurred repeatedly for the last 12 years.

In 2001, a betamethasone injection produced from a nonsterile powder and distributed by a compounding pharmacy in California was linked to illness and death in multiple patients. The betamethasone apparently became contaminated with *Serratia* bacteria

when a 300-milliliter (ml) batch of the drug was being transferred into 5 ml vials for sale to at least 60 San Francisco-area physicians, hospitals and clinics. Of the 38 patients known to have received the drug via spinal injections for back pain, 13 were hospitalized and five contracted meningitis, three of whom died.

When viewed in hindsight, the following excerpt from a scathing editorial about the dangerous and inadequate oversight of compounding pharmacies published in the *San Francisco Chronicle* soon after the California outbreak is both chilling and prophetic given the current meningitis outbreak:

The recent deaths and disease resulting from a contaminated batch of pharmacy medicine should be a jarring warning to public health officials. Either step up oversight and regulation of pharmacies or swallow hard and brace for an even more devastating catastrophe.

We strongly agreed with the editorial writer’s assessment then and still do. Because public health officials at the state and federal levels, particularly at the FDA, failed to heed the warning, we are now experiencing the predicted “more devastating catastrophe.”

Another example occurred in 2002, when four patients with back pain developed a rare form of fungal meningitis after receiving spinal injections of a steroid contaminated with the fungus *Exophiala* that was produced by a compounding pharmacy in South Carolina. One patient died as a result of the infection. A fifth patient developed an infection of the sacroiliac joint after receiving an injection of the same tainted steroid.

More recently, in 2009, 19 patients in six hospitals in Alabama developed life-threatening blood stream infections (sepsis) after receiving intravenous nutritional solutions contaminated with the bacteria *Serratia marcescens*, prepared by a compounding pharmacy in Birmingham, Ala. Nine of these patients died.

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And in May 2012, the CDC reported an outbreak of fungal eye infections linked to contaminated eye drugs prepared by a compounding pharmacy in Florida. Thirty-three eye surgery patients across seven states were affected.

These cases represent just a few examples of contaminated drugs prepared by compounding pharmacies that have led to serious outbreaks. Thus, the current fungal meningitis outbreak should surprise no one.

### Many deserve blame

Numerous investigations into this outbreak are ongoing, and litigation targeting the producer of the tainted drug and health care providers who used it will certainly take years to resolve. Blame for this disaster will undoubtedly rest with many parties: NECC, health care facilities and providers who chose to use a drug lacking both FDA approval and evidence of sterility, trade associations and professional groups representing compounding pharmacies that have vigorously resisted federal regulatory oversight of their members, state and federal regulators, and Congress. As discussed earlier, at the federal level, the FDA bears significant responsibility.

### Advice for patients

There are some legitimate medical reasons for using compounded drugs, but they are extremely limited.

Whenever a commercially available, FDA-approved, brand-name or generic version of a drug made by a pharmaceutical company is available for a particular disease or condition, that drug should always be selected over a version of the drug produced by a compounding pharmacy. This is particularly true for drugs intended to be injected, which must be sterile.

It is likely that most, if not all, of the back-pain patients who received injections of NECC's contaminated steroid drug were unaware that they were

### A Timeline of the Meningitis Outbreak

**May 21, 2012** — NECC produces the first of three lots of methylprednisolone acetate later found to be contaminated with mold.

**Sept. 18, 2012** — The first case of fungal meningitis linked to contaminated steroid produced by NECC is confirmed.

**Sept. 25, 2012** — NECC voluntarily recalls three lots of injectable steroid linked to the fungal meningitis outbreak (17,676 doses had been shipped to customers in 23 states).

**Sept. 26, 2012** — FDA investigators begin inspecting the NECC facility.

**Oct. 3, 2012** — NECC voluntarily shuts down.

**Oct. 4, 2012** — 35 cases of fungal meningitis, including five deaths, have been reported to the Centers for Disease Control (CDC).

**Oct. 5, 2012** — The FDA announces its investigation of the fungal meningitis outbreak. The FDA and CDC recommend that all health care professionals cease using any product produced by NECC.

**Oct. 6, 2012** — NECC voluntarily recalls all of its products in circulation.

**Oct. 16, 2012** — Agents from the FDA's Office of Criminal Investigation and local authorities raid the NECC facility.

**Oct. 26, 2012** — The FDA issues findings from NECC facilities inspections, conducted by the agency between Oct. 1 and Oct. 26, 2012. Numerous observations of poor sanitary and sterility conditions and procedures are noted.

**Nov. 1, 2012** — The FDA and CDC announce that bacterial contamination has been found in two other injectable drugs made by NECC.

**Nov. 14, 2012** — The Subcommittee on Oversight and Investigations of the U.S. House of Representatives Committee on Energy and Commerce hold a hearing investigating the fungal meningitis outbreak. In total, CDC has received reports of 451 cases of fungal meningitis, resulting in 32 deaths, and 10 peripheral joint infections linked to tainted injectable steroid produced by NECC.

**Nov. 15, 2012** — The U.S. Senate Committee on Health, Education, Labor, and Pensions holds a hearing investigating the fungal meningitis outbreak.

receiving a compounded drug that was not approved by the FDA or made in accordance with the high quality standards required for drug companies. If your doctor is going to give you an intravenous or injected medicine, you should inquire whether the drug was made by a pharmaceutical company or a compounding pharmacy. If there is uncertainty about the source of the drug, ask to see the FDA-approved drug label.

If the drug was produced by a compounding pharmacy, you should demand an explanation for why a compounded version of the drug is to be used and whether a generic or brand-name version of the same drug from a

pharmaceutical company is available. If such FDA-approved versions exist but are out of stock or in short supply, ask whether the treatment can be delayed until the higher-quality, safer, FDA-approved version becomes available.

You should be very skeptical of physicians or pharmacies promoting compounded drugs. If a physician or pharmacist tells you the only treatment for your condition is a compounded drug and you don't need emergency treatment, get a second opinion.

*To learn about Public Citizen's advocacy work on the topic of compounding pharmacies, visit [www.citizen.org/hrpublications](http://www.citizen.org/hrpublications). ♦*

## HRG Works for You!

### Our latest work involves the fungal meningitis outbreak and a dangerous cholesterol drug

The work of Public Citizen's Health Research Group (HRG) doesn't end with our *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses 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
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **Letter to the Secretary of Health and Human Services Calling for Expanded Investigation into Deadly Meningitis Outbreak — 11/19/2012** — Public Citizen urges the Secretary of the Department of Health and Human Services (HHS) to investigate whether financial incentives created by inconsistent Medicare drug reimbursement policies of the Centers for Medicare and Medicaid Services (CMS), combined with inadequate Food and Drug Administration (FDA) action, fostered the recent outbreak of life-threatening fungal meningitis caused by tainted steroid injections.
- **Response to Senate HELP Committee's Questions Regarding Compounding Pharmacies — 11/2/2012** — Public Citizen responds to the questions posed by the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) regarding the widespread fungal meningitis outbreak linked to contaminated injectable steroids produced by a compounding pharmacy. We urge the HELP Committee and other congressional committees responsible for overseeing the activities of the FDA to fully investigate the role this agency, as well as others, played in allowing the outbreak to occur.
- **Letter to Secretary of Health and Human Services on FDA Oversight Failures in Light of Meningitis Outbreak — 10/24/2012** — Public Citizen urges HHS to appoint an independent entity, such as the HHS Office of Inspector General, to conduct a thorough investigation into how the FDA failed to use its established regulatory authority to protect the public from the dangerous practice of large-scale drug compounding.
- **Testimony on Mipomersen to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee — 10/18/2012** — Public Citizen testifies that the agency should not approve the proposed cholesterol drug mipomersen because the study supporting approval was unethical in withholding an effective therapy from patients with a rare disease, and the drug itself causes a plethora of serious side effects.
- **Commentary on CNN.com: Deadly Meningitis Outbreak Was Completely Avoidable — 10/16/2012** — In an invited commentary, Public Citizen reports that the ever-expanding outbreak of life-threatening fungal meningitis in back pain patients linked to steroid injections prepared by a compounding pharmacy is a public health catastrophe made more tragic by the fact that it was avoidable.

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Visit [www.citizen.org/hrgpublications](http://www.citizen.org/hrgpublications) to read full reports and testimonies as HRG fights for government accountability in the interest of the public's health.

# As Online Drug Promotion Proliferates, Regulations Lag Behind

The Internet can justifiably be considered a double-edged sword — breathtakingly convenient in its ease of access to a universe of information but also rife with inaccurate and potentially dangerous content. The ability to distinguish between truth and falsehood is critically important in an era in which an ever-increasing number of people are seeking out health information online. Three-fourths of adults report having searched online for health information on sites such as Google, with 62 percent having done so within the past month.

This trend has not been lost on the pharmaceutical industry, as the Internet has emerged as a popular marketing medium for drug companies. Advertising costs on the Internet are generally lower than on television or in print, and the potential reach is much greater. Unlike traditional media, the Internet also offers the possibility of targeting individual consumers' personal characteristics and content preferences, a marketer's dream that was impossible prior to the digital age.

Every major drug company has expanded into online marketing, with several companies maintaining their own blogs, Facebook pages and Twitter accounts showcasing the latest company news or research related to current or emerging products. The industry as a whole spent more than \$1 billion on online marketing in 2011, with much of the money going to paid advertising on commercial sites such as Google and health-related websites.

Unfortunately, the regulations governing such marketing have not kept pace with current trends. The Food and Drug Administration (FDA) does not have comprehensive guidelines on the online marketing of drugs and has yet to finalize guidance on social media marketing rules. The agency held a hearing and solicited public comments on the issue in November 2009, but no

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final guidelines have yet resulted. The lack of clear rules on what is permissible in the arena of online drug promotion has predictably led to a litany of questionable marketing practices that continue to go unchecked.

## **“Misleading” and “misbranded” replaced by bait-and-switch**

The widespread use of so-called “sponsored links” on search engines is a case study in deceptive marketing by the pharmaceutical industry. These links are displayed at the top of the results page following a query on a search engine such as Google or Bing, and they are the first results one sees after searching for a particular medical condition. In the past, these links would prominently display the name of the drug in a hyperlink to the product's website, with a one-line statement touting the drug's benefits. Another statement, typically underneath the promotional one, would direct the user to a separate website displaying adverse effect information. Under this system, the adverse effects, while not immediately available, would be only one click away. This was the drug companies' way of conforming with the long-standing FDA regulation requiring significant adverse effect information to be displayed with any promotional piece.

In March 2009, the FDA sent out warning letters to several pharmaceutical companies stating that the

“one-click rule” would no longer be permitted because the lack of prominently displayed adverse effect information rendered the advertisements “misleading.” The agency informed the companies that all sponsored links would have to include significant adverse effects within the ad itself. Because the space constraints of a one-line advertisement made the new guidelines impossible to follow, most companies responded by removing their ads altogether.

Despite this attempt to address misleading promotion, the FDA continued to allow the more deceptive practice of the “vanity URL,” in which a paid ad presents itself in online search results as an informative site educating readers about a particular disease. Vanity URLs come with names such as [www.understand-high-blood-pressure.com](#) that then redirect the user to the official promotional site for a product treating the disease (in this case, nebivolol [BYSTOLIC]). Within three months of the FDA's 2009 warning letters, vanity URLs had replaced branded ads as the most common type of sponsored link used by the pharmaceutical industry.

The drug company Merck acknowledged that vanity URLs are “potentially deceptive” in a February 2010 letter urging the FDA to reinstate the one-click rule. Although the FDA did not accede to the reinstatement request, the agency has yet to take a position on vanity URLs, instead stating that it is working on this issue as part of its broader guidelines, still pending, on online pharmaceutical promotion.

For its part, Google unfortunately allows the pharmaceutical industry to use vanity URLs, a privilege it does not generally grant to other advertisers. Google policy states that it allows the practice “... in limited situations.”

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## Raising awareness or creating artificial needs?

Not all drug industry-sponsored links purporting to lead consumers to online health information are misleading. Some link to websites that do seem to contain only informational, disease-specific content. These so-called “help-seeking” websites operated by drug companies (e.g., [www.asthma.com](http://www.asthma.com)) are exempt from FDA regulations as long as they do not recommend any specific drug to treat the disease in question.

Although the drug industry argues that help-seeking websites are an innocuous way of raising public awareness of a disease, the sites are not altruistic. They also function as advertisements, benefitting drug companies in several ways. First, the websites usually contain direct links to the sponsoring company’s brand-name drug for the given condition. The websites are also often subtly linked to a company’s explicit promotional sites through design characteristics, such as color schemes and typefaces. In some cases, the information refers to the company’s drugs in all but name only, prompting FDA warnings on a number of occasions.

More generally, however, the ads are just the latest version of a strategy as old as the drug industry itself to “raise awareness” of myriad diseases in order to create patient “needs” resulting in new and ever-larger markets for the most lucrative drugs. Indeed, the corporate marketing departments that create such sites are well aware of the linked phenomena of “disease invention” and “disease promotion.”

Disease invention works by creating new disease categories for which drugs can be marketed. Health journalist Martha Rosenberg characterizes the phenomenon by stating that “when the medication is ready, the disease (and patients) will appear.” Examples abound.

The relatively new disease “Low T” (low testosterone) is a condition that is being heavily promoted by Abbott Laboratories, the maker of testosterone

## Declining warnings and absent consequences

The lack of clear rules governing online drug promotion is part of a larger trend of decreasing enforcement of misleading drug promotion, online and otherwise, by the FDA in recent years. Over the last decade, the number of warning letters sent by the agency to drugmakers for illegal marketing activities has declined from 100-150 per year in the late 1990s to 31 in 2011. The warning letters themselves effectively represent a hollow enforcement tool in that they do not result in penalties or other sanctions for the offending companies. Although the FDA has had the authority since 2007 to fine companies issuing misleading direct-to-consumer advertisements, the agency acknowledges that as of October 2012, no such fines have yet been issued. Companies therefore know that in all likelihood, they will first be granted the opportunity, through a warning letter, to correct the ad and thus avoid any penalties. Given this, companies can continue to experiment with increasingly deceptive and surreptitious marketing tactics until slapped on the wrist by a warning letter bearing no consequence.

gel (ANDROGEL). Testosterone levels decrease as a normal function of age, declining by about 1 percent per year beginning at age 30. Thus, just about every man past middle age could be characterized as having Low T. With this in mind, Abbott designed a help-seeking website, [www.isitlowt.com](http://www.isitlowt.com), replete with images of depressed-looking men. For added effect, a section for spouses reassures women: “It’s not you. It could be Low T.” Site visitors can request more information about the condition (sent to them by Abbott) or simply click on “treatment options,” which redirects them to the promotional site for ANDROGEL.

Although ANDROGEL is indicated for men with lower than normal testosterone levels, the medical community is unsure of what constitutes “normal” testosterone levels or whether below-normal levels actually cause a patient’s symptoms. Furthermore, because symptoms of this illness are vague and readily generalizable to the majority of the older male population, many older men with normal testosterone levels are undoubtedly pressuring their doctors to prescribe them the all-in-one virility pill.

Even in cases of more established diseases, help-seeking ads can give healthy patients the false impression that they have a given condition. This is especially true for diseases with nebulous

or subjective symptoms, such as depression, that are more easily prone to being pathologized. People with a simple case of the blues can be made to believe that they suffer from a medical condition, especially if an easy solution is proffered in pill form. And patients whose symptoms do in fact qualify as evidence of depression may be persuaded to pursue medical treatment even though their conditions may improve without drugs.

## A vulnerable population

People searching for health information online are often at their most vulnerable, struck down with a debilitating disease or desperately looking for treatments for an ailing family member. This is precisely the time that they are most apt to be influenced by a fleeting ad appealing to their precarious emotional state. Online drug marketing exploits this emotional state by steering otherwise rational people to make irrational medical decisions. Patients should expect some measure of regulatory protection from the most deceptive promotional practices. ♦

# A Single-Payer System, Not the ACA, Is the Remedy for the National Health Crisis

**W**ith the U.S. Supreme Court's upholding of the Affordable Care Act (ACA) in 2012, health care reform found itself front and center in our national conversation this year. One of the best, most critical responses to the ACA was written by our colleagues at Physicians for a National Health Program, or PNHP, the largest and most progressive group of physicians in the country. With more than 18,000 members and chapters across the U.S., the organization was founded in 1987 by longtime Harvard Medical School faculty members and former primary care physicians Dr. Steffi Woolhandler and Dr. David Himmelstein.

Following the Supreme Court's ruling, PNHP issued a fact sheet highlighting the inadequacy of the ACA and stressing the need for a single-payer, improved-Medicare-for-all system. This sentiment was echoed by Public Citizen president Robert Weissman, who stated on the day of the Supreme Court ruling that the legislation "will predictably fail to solve our nation's health care crisis."

What follows is PNHP's single-payer information fact sheet, reprinted with permission, which also represents Public Citizen's stance on the failings of the ACA legislation.

## Summary

- Although the Court has ruled [the ACA] constitutional, it will not work to remedy the health crisis. Single-payer is the only constitutional option for **truly universal** coverage.
- Instead of eliminating the root of the problem — the profit-driven, private health insurance industry — this legislation hands them \$557 billion in taxpayer money through 2020. **The total windfall to private insurers from the ACA, including tax subsidies, consumers' share of premiums, and overhead and profits from Medicaid managed care plans, is well over \$1 trillion,**

**according to a Bloomberg Government study. Insurers will keep about \$174 billion — \$22 billion a year — for profit and administrative costs.** This money will enhance their financial and political power, and with it their ability to block future reform.

- As noted by President Obama in a July 22, 2009, press conference, "unless you have what's called a single-payer system in which everybody is automatically covered, then you're probably not going to reach every single individual." In other words, single-payer is the only way to actually achieve truly universal coverage.
- Based on the evidence, we call for immediate Congressional passage of single-payer national health insurance, improved Medicare for All, based on its potential to eliminate financial barriers to care, improve efficiency, and control costs.

## Access

- The **ACA will cover less than half of the uninsured** even when fully implemented, leaving 26 to 27 million people uninsured in 2019, according to the Congressional Budget Office.
- As a result, at that date an estimated **26,000 people will die every year** due to lack of health insurance, on top of an incalculable toll of suffering.
- "**Unaffordable underinsurance**" will become the new norm as millions of middle-income people are required to buy **unaffordable, skimpy health insurance policies that will consume up to 9.5 percent of family income** but leave patients unable to access care due to high deductibles, co-pays, co-insurance, and other out-of-pocket costs.
- Nearly half (48 percent) of families with **chronic conditions** with high deductible health plans report **financial burdens related to medical costs.**

- People with employer-based coverage will continue to lack meaningful choices, instead being **locked into their plan's limited network of providers**, facing ever-rising costs and continuing erosion of their health benefits. Already nearly one-third of large employers are offering high deductible health plans.
- In 2010, **75 million working age adults went without necessary care due to costs**, 73 million reported having trouble paying bills or were in medical debt, and a quarter of those with chronic conditions skipped care due to cost.

## Costs

- **Costs will continue to skyrocket** because the law contains no effective cost-control measures. The cost of employer sponsored health coverage has more than doubled since 2000 and now averages \$15,073 for family coverage.
- This year **U.S. health spending will top \$2.8 trillion, \$8,936 per capita, 17.6 percent of GDP**, "crowding out" spending by government, business, and families on other needed goods and services.
- **30 million Americans were contacted by collection agents for unpaid medical bills** in 2010, up from 22 million in 2005, according to The Commonwealth Fund.
- **[ACA] will not reduce medical bankruptcy.** In Massachusetts, the model for the federal reform law, most of the new coverage is bare-bones, high-deductible health plans, which fail to protect families from financial ruin in the event of illness. According to research led by PNHP members, **the rate of medical bankruptcy in MA has not declined** since the reform was implemented. Nationally, 78 percent of those bankrupted by illness or injury are insured at the

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start of their illness, including 60.3 percent who have private coverage.

- **[ACA] will not increase efficiency.** Overhead and bureaucracy, which already consume 31 percent of every health care dollar, will continue to rise. Most of the 18,000 new jobs created in Massachusetts as a result of the reform law are devoted to administrative tasks (management, business and financial operations, office support, medical records, health information, etc.).

## Safety net and women's health

- The law will drain **about \$40 billion from Medicare payments** to safety-net hospitals, threatening the care of the tens of millions who will remain uninsured.
- **Women's reproductive rights will be further eroded**, thanks to the burdensome segregation of insurance funds for abortion and for all other medical services.
- The much-vaunted insurance regulations — e.g., community rating — are riddled with loopholes, thanks to the central role that insurers played in crafting the legislation. Older people can be charged up to three times more

than their younger counterparts, **and large companies with a predominantly female workforce can be charged higher gender-based rates at least until 2017.**

## Good provisions could have been enacted alone

- The salutary measures contained in this law, e.g. **additional funding for community health centers** and **allowing children up to age 26 to stay on a parent's policy**, could have been enacted on a stand-alone basis.
- Similarly, the **expansion of Medicaid** — a woefully underfunded program that provides substandard care for the poor — could have been done separately, along with an increase in federal appropriations to upgrade its quality.

## Need for evidence-based reform

- This law's design reflects political considerations, not sound health policy. As physicians, we cannot accept this inversion of priorities.
- We seek evidence-based remedies that will truly help our patients, not placebos.
- A genuine remedy is in plain sight. Sooner rather than later, our nation

will have to adopt a single-payer national health insurance program, an improved Medicare for all. Only a single-payer plan can assure truly universal, comprehensive and affordable care to all.

- **By replacing the private insurers with a streamlined system of public financing**, our nation could **save \$400 billion annually in unnecessary, wasteful administrative costs.** That's enough to cover all the uninsured and to upgrade everyone else's coverage without having to increase overall U.S. health spending by one penny.
- Moreover, only a single-payer system offers **effective tools for cost control like bulk purchasing, negotiated fees, global hospital budgeting and capital planning.**
- Polls show nearly two-thirds of the public supports such an approach, and a recent survey shows **59 percent of U.S. physicians support government action to establish national health insurance.** All that is required to achieve it is the political will.

*To learn more about Physicians for a National Health Program and to read the full content of the fact sheet, visit [PNHP.org](http://PNHP.org). ♦*

## OUTRAGE, from page 12

### 4. Use only generic statins when initiating lipid-lowering drug therapy.

- All statins are effective in decreasing mortality, heart attacks, and strokes when dose is titrated to effect appropriate LDL cholesterol reduction.
- Switch to more expensive brand-name statins (atorvastatin [LIPITOR] or rosuvastatin [CRESTOR]) only if generic statins cause clinical reactions or do not achieve LDL cholesterol goals.

### 5. Don't use DEXA [bone mineral density] screening for osteoporosis in women under age 65 years or men under 70 years with no risk factors.\*\*

- Not cost-effective in younger, low-risk patients, but cost-effective in older patients.

*\*\*Risk factors include but are not limited to fractures after age 50 years, prolonged exposure to corticosteroids, diet deficient in calcium or vitamin D, cigarette smoking, alcoholism, thin and small build.*

*[Health Letter editor's note: We disagree with the first bullet in item 4, since neither rosuvastatin (CRESTOR) nor fluvastatin (LESCOL) has been*

*shown to decrease death, heart attacks or strokes in people with elevated cholesterol levels.]*

Public Citizen's bottom line: When it comes to unnecessary diagnostic testing, patients are advised to **just say no.**

*Reprinted with permission from: Good Stewardship Working Group. The "Top 5" Lists in Primary Care: Meeting the Responsibility of Professionalism. *Arch Intern Med* 2011;171(15):1385-1390. ♦*

# Product Recalls

## October 4, 2012 – October 31, 2012

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](http://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

**Doxazosin tablets**, 2 mg, 100-count bottles. Volume of product in commerce: 24,331 bottles. Cross contamination with other products: During stability testing, chromatographic review revealed extraneous peaks identified as acetaminophen and codeine. Lot #: A 303M, expiration date 06/2014. Mylan Pharmaceuticals Inc.

**Kombiglyze XR (saxagliptin and metformin HCl extended-release) tablets**, physician sample — not for sale, 6 tablets per carton, 2.5 mg/1000 mg. Volume of product in commerce: 117,049 sample cartons. Some physician sample cartons were incorrectly labeled as Kombiglyze XR 2.5mg/1,000mg on the external package carton, whereas the contents were Kombiglyze XR 5 mg/500 mg blister packaged tablets. The individual blister units are labeled correctly. Multiple lots affected. Bristol-Myers Squibb Company.

**Kombiglyze XR (saxagliptin and metformin HCl extended-release) tablets**, physician sample — not for sale, 7 tablets per carton, 5 mg/500 mg. Volume of product in commerce: unknown. Some physician sample cartons were incorrectly labeled as Kombiglyze XR 2.5mg/1,000mg on the external package carton, whereas the contents were Kombiglyze XR 5 mg/500 mg blister packaged tablets. The individual blister units are labeled correctly. Multiple lots affected. Bristol-Myers Squibb Company.

**Lutera (levonorgestrel and ethinyl estradiol) tablets**, 0.1 mg/0.02 mg, inert tablets, 28-count tablets per dispenser packaged in 6 tablet dispensers per carton. Volume of product in commerce: 67,860 cartons. Cross contamination with other products: Certain lots could potentially be contaminated with trace amounts of Hydrochlorothiazide (HCTZ). Lot #: 517921AA, 517921AB, 517922AA, 517922AB, 517923AA and 517923AB, expiration date 03/31/2014. Watson Laboratories Inc.

**Moexipril HCl tablets**, 7.5mg, 100 tabs. Volume of product in commerce: 2,267 bottles. Non-conformity dissolution failure result found during routine stability testing at the six-month test interval. Lot #: 2012028142, expiration date 01/2014. Paddock Laboratories, Inc.

**Necon 10/11 (norethindrone and ethinyl estradiol) tablets**, 0.5 mg/35 mcg, 1 mg/35 mcg, inert tablets, 28-count tablets per dispenser packaged in 6 tablet dispensers per carton. Volume of product in commerce: 1,684 cartons. Cross contamination with other products: Certain lots could potentially be contaminated with trace amounts

of Hydrochlorothiazide (HCTZ). Lot # 512642B, expiration date 08/31/2013. Watson Laboratories Inc.

**Necon 1/35-28 (norethindrone and ethinyl estradiol) tablets**, 1 mg/35 mcg, inert tablets, 28-count tablets per dispenser packaged in 6 tablet dispensers per carton. Volume of product in commerce: 6,466 cartons. Cross contamination with other products: Certain lots could potentially be contaminated with trace amounts of Hydrochlorothiazide (HCTZ). Lot #: 514743AB, expiration date 09/30/13. Watson Laboratories Inc.

**Nimodipine capsules**, 30 mg, 30-count unit dose capsules (5x6 blister cards per carton). Volume of product in commerce: 2,424 cartons. Crystallization: Presence of crystals of Nimodipine within the capsule solution. Lot #: 3305.039B, expiration date 07/2013. Caraco Pharmaceutical Laboratories.

**Nimodipine capsules**, 30 mg, 100-count unit dose capsules (25x4 blister cards per carton). Volume of product in commerce: 2,675 cartons. Crystallization: Presence of crystals of Nimodipine within the capsule solution. Lot #: 3305.039A, expiration date 07/2013. Caraco Pharmaceutical Laboratories.

**Perphenazine tablets**, 8 mg, 100-count tablets per bottle. Volume of product in commerce: 2,755 bottles. Tablet separation: Possibility of cracked or split coating on the tablets. Lot #: C1130511A, expiration date 05/2013. Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals.

**Zenchant (norethindrone and ethinyl estradiol) tablets**, 0.4 mg/0.035 mg, 28-count tablets per dispenser packaged in 6 tablet dispensers per carton. Volume of product in commerce: 12,333 cartons. Cross contamination with other products: Certain lots could potentially be contaminated with trace amounts of Hydrochlorothiazide (HCTZ). Lot #: 514767AA, expiration date 03/31/14. Watson Laboratories Inc.

**Zovia (ethynodiol diacetate and ethinyl estradiol) tablets**, 1 mg/35 mcg, inert tablets, 28-count tablets per dispenser packaged in 6 tablet dispensers per carton. Volume of product in commerce: 30,267 cartons. Cross contamination with other products: Certain lots could potentially be contaminated with trace amounts of Hydrochlorothiazide (HCTZ). Lot #: 515622AA, 515623AA and 515623BA, expiration date 09/30/13. Watson Laboratories Inc.

## 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](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### Name of Product; Problem; Recall Information

**Bicycle Wheel Rim Tape.** The rim tape can fail and break under pressure. When this happens, the inner tube of the bicycle can puncture or burst. This poses a fall hazard to the rider. FLO Cycling, at (888) 959-8312 or <http://www.flocycling.com>.

**Bistro High Chairs.** The front openings between the tray and seat bottom and on the side openings of the high chair between the armrest and seat bottom can allow a child's body to pass through and become entrapped at the neck. This poses a strangulation hazard to young children if the belt is not engaged. In addition, exposed springs between the seat and armrest on both sides of the high chair can create a pinch hazard to the child. Dream On Me Inc., at (877) 201-4317 or [www.dreamonme.com](http://www.dreamonme.com).

**Ceramic Beer Tap Handles.** The ceramic beer tap handle can break during normal use, posing a laceration hazard to consumers. Taphandles, at (877) 855-6383 or [www.taphandles.com/recall](http://www.taphandles.com/recall).

**Children's Upholstered Toddler Chairs.** Staples in the binding on the back of the chair may come loose, posing a laceration or choking hazard if swallowed. Trend Lab, at (866) 814-7978 or [www.trend-lab.com](http://www.trend-lab.com).

**Crush Series: Perch, Stoop and Ledge Treestands for Hunters.** The tree stand's hanging strap assembly could dislodge from the tree stand or fail to restrain or hold properly on the tree, posing a fall hazard. Summit Treestands, LLC, at (855)373-9808 or [www.summitstands.com](http://www.summitstands.com).

**Double Dazzler Light Show.** The battery in the toys can overheat and pose a burn hazard. Imagine Nation Books, at (800) 917-0213 or [www.booksarefun.com/recall](http://www.booksarefun.com/recall).

**Eddie Bauer Rocking Wood Bassinets.** The bottom locking mechanism can fail to lock properly if a spring is not installed, allowing the bassinet to tip to one side and cause infants to roll to the side of the bassinet. This poses a suffocation hazard to infants. Dorel, at (877) 416-0165 or [www.djgusa.com](http://www.djgusa.com).

**ElliptiGO 11R Outdoor Elliptical Cycles.** The drive arm on the ElliptiGO cycles can crack or break during use, posing a fall hazard to the user. ElliptiGO, at (888) 551-0117 or [www.elliptigo.com/recall.html](http://www.elliptigo.com/recall.html).

**Fleece Hoodie and T-shirt Sets.** The surface coating on the zipper of the fleece hoodie and t-shirt sets contain excessive levels of lead, violating the federal lead paint standard. Children's Apparel Network, at (800) 919-1917 or [www.childrensapparelnetwork.com](http://www.childrensapparelnetwork.com).

**Graco Classic Wood Highchairs.** The high chair's seat can loosen or detach from the base, posing a fall hazard to the child. Graco, at (800) 345-4109 or [www.gracobaby.com](http://www.gracobaby.com).

**Happy Swing II Infant Swings.** The opening between the tray and seat or the grab bar and seat can allow a child's body to pass through and become entrapped at the neck, posing a strangulation hazard to young children if the belt is not engaged. Dream On Me, at (877) 201-4317 or [www.dreamonme.com](http://www.dreamonme.com).

**Hatsan Striker Air Rifles.** The air rifles can fire unexpectedly when closing the action during the cocking process. HatsanUSA, Inc., at (877) 278-4448 or [www.hatsanusa.com/striker-recall](http://www.hatsanusa.com/striker-recall).

**JELD-WEN and Reliabilt Interior Bifold Doors.** The lower pivot pin can break, causing the door to disengage from the overhead track, which poses an impact hazard. JELD-WEN, at (877) 228-4888 or [www.jeld-wen.com/newhardware](http://www.jeld-wen.com/newhardware).

**Sharper Image USB Wall Chargers.** The chargers can overheat and smoke, posing fire and burn hazards to consumers. Atomi, at (800) 790-1440, or e-mail [info@atominy.com](mailto:info@atominy.com).

**Step Stool.** The top step/standing platform can break, posing a fall hazard to consumers. Tricam Industries, at (855) 336-0360 or [www.gorillaladders.net](http://www.gorillaladders.net).

**Tree Stands for Hunters.** The snap-hook assemblies can fail, causing the tree stand and the user to fall to the ground. Rivers Edge, at (866) 527-9690 or [www.riversedgesafetyrecall.com](http://www.riversedgesafetyrecall.com).

**ValcoBaby "Joey" Booster Toddler Seats for Strollers.** The spring button mechanism securing the booster toddler seat to the baby stroller can disengage, allowing for the carried toddler to fall. ValcoBaby, at (800) 610-7850 or [www.valcobaby.com/warranty-registration/recall-joey.html](http://www.valcobaby.com/warranty-registration/recall-joey.html).

## Outrage of the Month! Top Five Examples of Overdiagnosis and Unnecessary Treatment

The useful book by Dr. H. Gilbert Welch, “Overdiagnosed: Making People Sick in the Pursuit of Health” (Beacon Press) has previously been discussed in *Health Letter*. This book highlights the ways in which the conventional wisdom of the medical establishment — that early diagnosis of disease is always best — can not only fail to help patients but can also expose them to unneeded harm.

A recent article in the *Archives of Internal Medicine* offered examples of “diagnostic tests or treatment that are commonly ordered but that offer limited benefits or carry risks that outweigh their benefits.” The text below is excerpted from this article and outlines five best practices in internal medicine to avoid overdiagnosis.

2. Don't obtain blood chemistry panels (e.g., basic metabolic panel) or urinalyses for screening in asymptomatic, healthy adults.
  - Only lipid screening [cholesterol, etc.] yielded significant numbers of positive results among asymptomatic patients.
  - Screen for type 2 diabetes mellitus in asymptomatic adults with hypertension.

### 3. Don't order annual ECGs [electrocardiograms] or any other cardiac screening for asymptomatic, low-risk patients.

- Little evidence that detection of coronary artery stenosis in asymptomatic patients at low risk for coronary heart disease improves health outcomes.
- False-positive tests are likely to lead to harm through unnecessary invasive procedures, overtreatment, and misdiagnosis.
- Potential harms of this routine annual screening exceed the potential benefit.

### 1. Don't do imaging [MRI or CT scan] for low back pain within the first six weeks unless red flags\* are present.

- Imaging of the lumbar spine before six weeks does *not* improve outcomes but does increase costs.
- Low back pain is the fifth most common reason for all physician visits.

\*Red flags include but are not limited to severe or progressive neurological deficits or when serious underlying conditions such as osteomyelitis (bone infection) are suspected

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