



Industry Lobbies to Weaken Medical Device Oversight

The medical device industry is engaged in a massive lobbying campaign designed to weaken the already lax oversight of medical devices and to accelerate the already too-quick review of high-risk medical products, a recent Public Citizen report found. The report, “Substantially Unsafe: Medical Devices Pose Great Threat to Patients; Safeguards Must Be Strengthened, Not Weakened,” was issued in anticipation of a Feb. 15, 2012, hearing in the U.S. House of Representatives on reauthorization of the Medical Device User Fee Act (MDUFA).

As the \$350 billion industry pushes for a quicker and easier device review process, Public Citizen instead calls for stronger standards on par with those governing newly proposed drugs. The following are key findings and recommendations presented in Public Citizen’s report.

Medical device industry lobbying and campaign contributions

Regulation of medical devices — including such products as heart and brain stents to prop open blocked arteries, artificial hips and implantable heart defibrillators — is at a crossroads as Congress considers reauthorization of MDUFA.

Enacted in 2002 and renewed in 2007, the MDUFA user-fee program requires the Food and Drug Administration (FDA) to collect application fees from companies seeking clearance or approval to market new medical devices. In exchange, the FDA must meet a set of

Table 1: Classifications of Recalls (by Fiscal Year)

	Recall Classification	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011*	Total
Class I Recall	Recall poses high risk	26	14	32	49	50	171
Class II Recall	Recall poses moderate risk	540	710	677	751	1,151	3,829
	Total	566	724	709	800	1,201	4,000

Source: Food and Drug Administration

*FY11 numbers may change when FDA aggregates data.

performance goals agreed upon by both the agency and industry.

The 2002 and 2007 enactments of MDUFA did not substantially change the fundamental regulatory framework for medical devices. However, the 2007 MDUFA reauthorization gave industry and other stakeholders the opportunity to make recommendations on various aspects of the user-fee program prior to the 2012 reauthorization. For example, the speed of review times, number of FDA reviewers overseeing a device application and industry application fees (called user fees) were put up for discussion.

The 2012 reauthorization process also gives industry, other stakeholders and Congress an opportunity to seek changes to other parts of the medical device statute that are unrelated to the user-fee program.

With reauthorization of the MDUFA bill up for debate, members of Congress already have introduced 14 bills (10 in the House and four in the Senate) that aim to accelerate devices’ path to the market, often by weakening measures intended to ensure patient safety. For example, the bills would water down already weak standards for FDA

clearance or approval of a new medical device, shift the emphasis of the FDA’s mission from protecting public health to promoting medical innovation, and weaken the financial “conflict of interest” prohibition against serving on the FDA advisory committee that oversees medical device approvals.

The bills reflect the industry’s concerted lobbying campaign. In 2011, the medical device industry spent \$33.3 million on lobbying, raising its total to \$158.7 million since 2007. In just the third and fourth quarters of 2011, at least 225 industry lobbyists — including 107 who previously worked for the federal government — lobbied members of Congress or executive branch officials on issues relating to medical device regulation.

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Table 2: Number of Device Submissions for Moderate- and High-Risk Devices (by Fiscal Year)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Total:	3,966	3,747	3,933	4,191	3,989

Source: Food and Drug Administration, MDUFA Performance Reports (2010)

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Additionally, in 2011, at least 36 device industry lobbyists hosted 40 separate campaign fundraisers for 31 members of Congress. Further, the device industry paid \$19.9 million in campaign contributions to federal candidates since the 2006 election cycle.

Members of a key House Energy and Commerce Committee health subcommittee with jurisdiction over medical devices received contributions from the device industry each election cycle that doubled those of the average House member. Actual sponsors of the 10 House bills seeking to weaken approval standards have received nearly three times as much.

Rising recalls for medical devices

The number of recalls for moderate- and high-risk medical devices in fiscal year 2011 (1,201) more than doubled from 2007 (566). The number of recalls specifically for high-risk devices in fiscal year 2011 was approximately double that of 2007. From 2006 through 2011, there were at least 171 high-risk recalls and 4,000 moderate- and high-risk recalls (see Table 1 on page 1).

The rising number of recalls has not been accompanied, nor can it be explained, by an increase in the number of new medical device applications submitted to the FDA (see Table 2 on this page). This suggests that the increase in recalls has been due to the decline in safety rather than an increase in the number of devices on the market.

The FDA defines recalls as events that “occur when a medical device is defective” or “when it could be a risk to health.” But recalls do not necessarily entail returning the products to the companies that made them. A recall

may involve actions such as inspecting the device for problems, repairing or re-labeling the device, issuing notifications of a problem or monitoring patients for health issues. Most recalls are initiated voluntarily by device manufacturers.

Recently recalled devices described in Public Citizen’s report include:

- Implantable pads (designed to shield breast tissue from radiation treatment for breast cancer) that shed small particles of tungsten into the breast, interfering with future screening tests needed to monitor for recurrence of the cancer.
- Infusion pumps that shut down unexpectedly or dispense incorrect doses of medicine given intravenously.
- Faulty implanted heart defibrillators that inappropriately deliver severely painful and potentially dangerous electrical jolts to the heart.
- Surgical clips (designed to clamp off arteries) that pop off, causing patients to bleed to death internally.
- Artificial hips that shed metal fragments into the bone and surrounding tissue, wearing away tissues and causing extreme pain and limited mobility.

FDA clearance and approval processes riddled with problems

The processes for approving or clearing new medical devices for sale are far less rigorous than those used to approve new drugs. For instance, the processes involving devices settle for a “reasonable assurance” that a proposed device is safe and effective, whereas drug

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approvals require the higher standard of “substantial evidence” of effectiveness, according to FDA drug laws.

For approval of most new drugs, the FDA requires at least two well-designed, randomized, controlled clinical trials conducted with people. In contrast, for most high-risk medical devices — called class III devices — approved by the FDA under a process known as a premarket approval application (PMA), the FDA requires only one controlled study. In many cases, the quality of the design of such studies is lower than that for most clinical trials for drugs (for example, many device studies are not randomized — with one group, but not the other, receiving the device).

Worse, the system for clearing more than 95 percent of moderate- and high-risk devices, called the 510(k) process, fails to incorporate even the most basic safeguards. The 510(k) process involves a much less rigorous review by the FDA in comparison to the review that occurs under the PMA process. Very few products cleared through the 510(k) process are subject to clinical testing. The vast majority achieve clearance for sale based on a mere demonstration that they are substantially equivalent to existing devices already on the market (known as “predicate devices”).

Reliance on substantial equivalence as a proxy for a determination of safety is inherently flawed. The FDA has inadvertently amplified the dangers of relying on substantial equivalence by executing a series of rulings that have permitted more devices to qualify as substantially equivalent and, thus, to find their way to the market under the lenient 510(k) process. The purportedly similar devices are often significantly different from their predicates.

This 510(k) clearance process is especially dangerous because most of the products already on the market that serve as predicate devices were themselves never tested in the first place to ensure that they were safe. Thus, a demonstration of a new product’s substantial equivalence to an existing

Table 3: Recommendations for Improving Medical Device Safety

Medical Device Review Procedure	Public Citizen’s Recommendations
510(k) process	<p>Short term:</p> <ul style="list-style-type: none"> • A device removed from the market because of concerns about safety or effectiveness should not be used as a predicate device for any new device submitted to the Food and Drug Administration (FDA) for clearance under the 510(k) process. • The FDA should re-evaluate the safety and effectiveness of any marketed medical device cleared under the 510(k) process when a predicate device upon which such clearance was based is removed from the market because of concerns about safety or effectiveness. • To facilitate efficient and effective tracking of the status of marketed devices that a manufacturer might use as a predicate for a proposed device, the FDA should be required to maintain an up-to-date and easily searchable database of eligible predicates. • All high-risk (class III) devices should be prohibited from receiving clearance under the 510(k) process. <p>Long term:</p> <ul style="list-style-type: none"> • Congress should mandate, in accordance with the Institute of Medicine’s recommendation, that the FDA replace the 510(k) process with a new approval process based on the standard of “substantial evidence” of safety and effectiveness.
PMA process	<ul style="list-style-type: none"> • The standard for approving any high-risk (class III) device under the premarket approval application (PMA) process should be changed to “substantial evidence” of safety and effectiveness. • Device submissions reviewed under the PMA process should provide data from at least two well-designed, randomized, controlled clinical trials, as is the case for most new drug applications.
Post-market surveillance	<ul style="list-style-type: none"> • The FDA should promptly implement a system of labeling all devices with unique identifiers to facilitate tracking of the devices to individual patients. • The FDA should require more thorough standards for reporting adverse events, similar to those used for drugs. • The FDA should use its authority to recall unsafe devices more frequently and consistently. • When a manufacturer initiates a recall, the recall must mean the removal of the device from the market. • The FDA should be required to systematically collect and assess data regarding all medical device recalls, whether mandated by the agency or voluntarily implemented by manufacturers.
Legal liability for defective devices	<ul style="list-style-type: none"> • Congress should pass legislation eliminating the provision in current law that preempts state civil court claims arising from defective devices approved by the FDA under the PMA process.

product proves little about safety.

The U.S. Supreme Court articulated this shortcoming in a 1996 decision in which it wrote: “Substantial equivalence determinations provide little protection to the public. ... If the earlier device poses a severe risk or is ineffective, then the latter device may also be risky or ineffective.”

In a report commissioned by the FDA and released last summer, the prestigious Institute of Medicine of the National Academy of Sciences concluded that the 510(k) process is so lacking in its ability to ensure safety that it needs to be scuttled.

Inadequate FDA monitoring of device safety after product approval or clearance

In addition to allowing far too many dangerous devices to reach the market, the FDA has proven inadequate at mitigating the damage from dangerous devices even after evidence of serious adverse events becomes apparent.

The current state of post-market surveillance for adverse events associated with the use of medical devices reflects an ineffective and wasteful system. The agency primarily depends on

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Scientific Fraud on the Rise

Its Impact on Patients and Research

The scientific community has long relied on peer review (the process of having experts in a certain field evaluate the research of their peers before it is accepted for publication) to maintain the integrity of medical evidence published in academic journals.

Yet in recent years, serious concerns have led to a number of high-profile retractions in some of the most prestigious publications. Is the peer-review process no longer enough to ensure the reliability of published data? Public Citizen explores the consequences and discusses solutions to the problem.

Effect on patient outcomes

Scientific fraud can influence physician prescribing habits and hurt patients. A 2003 article in the medical journal *Lancet* reported that two popular high blood pressure drugs — losartan (an angiotensin II receptor blocker) and trandolapril (an angiotensin-converting enzyme inhibitor) — were found to be much better at slowing the progression of nondiabetic renal disease when taken in combined form than either taken alone.

In 2009, however, the influential medical journal retracted the paper: An institutional investigation had revealed a number of ethical violations and concluded that the authenticity of the data could not be proven.

The damage may have already been done. A recent study published in the *Canadian Medical Association Journal* documented that between 2002 and 2006, about 5.4 percent of new users of either medication in Alberta, Canada, received this combination therapy. In comparing people using the combination of drugs from these two classes with those using either drug alone, the researchers found that the combination left patients more vulnerable to potentially life-

Scientific fraud, if undetected, can drag on for years and lead to further bad research.

threatening kidney toxicity. It is likely that a substantial number of patients may still be taking the drug combination, in spite of the risk of side effects.

Effect on other research

Scientific fraud, if undetected, can drag on for years and lead to further bad research. In 2006, a group of Duke University researchers appeared to have taken a great stride forward for personalized medicine when they published a report in *The New England Journal of Medicine (NEJM)* claiming to be able to predict the course of a patient's lung cancer using a device that could log the activity of the patient's genes.

A short time later, another team of researchers attempting to replicate the work began to raise questions about serious potential errors in the publication. Yet *NEJM* failed to retract the paper until 2010, when it was discovered that one of the lead researchers, Dr. Anil Potti, had lied on numerous documents and grant applications (including pretending to have been a Rhodes scholar in Australia — a clear sham because Rhodes scholars only attend Oxford University).

Potti has resigned his position at Duke, and the scandal has led to at least 10 retractions to date. Duke University halted three clinical trials involving cancer patients, and eight patients involved in those trials have sued the institution for failing to stop the trials sooner.

As this example shows, once an idea enters the field, it is hard to reverse course, because a researcher may

publish many times and influential papers are cited again and again by other researchers in newer articles. This carryover effect can be seen in another high-profile case involving Dr. Dipak Das, a University of Connecticut researcher who had gained attention for his work on the beneficial properties of resveratrol, a substance found in red wine.

An investigation by the university concluded that Das was guilty of 145 counts of fabrication and falsification of data, including manipulating images with Photoshop software. The university notified 11 scientific journals that had published studies by Das. The scandal understandably cast a shadow on the field of resveratrol research, which had already been the subject of some controversy.

Finally, in a case in which many of the researcher's articles have been cited at least 100 times, last November a well-known heart specialist, Dr. Don Poldermans, was fired from his position at a Dutch research center for scientific misconduct. He also has been accused in the Dutch media of faking academic data. He denies both claims.

Poldermans was widely known for his pathbreaking research on the effects of beta-blockers on the risk of complications during cardiovascular surgery. It is still unknown how many papers will be affected.

Tempering a growing trend

Overall, retractions in scientific papers seem to be on the rise. Between 2001 and 2011, the number of retractions in research journals increased more than 15-fold, while the total number of papers published increased by only 44 percent, according to a 2011 report by *The Wall Street Journal*. The report considered data on retraction notices published in research journals appearing in Thompson Reuters Web

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of Science, an index of 11,600 peer-reviewed journals worldwide.

While many of these retractions involve innocent mistakes (such as calculation errors or data mix-ups), a large number of others involve more serious charges: plagiarism, altered images or faked data. A 2010 analysis by R. Grant Steen, published in the *Journal of Medical Ethics*, examined 742 medicine and biology papers withdrawn between 2000 and 2010 and determined that 26.5 percent (197) were retracted for fraud (fabrication or falsification of data), while 73.5 percent (545) were retracted simply for error (retraction that was not fraud).

Part of the rise in the number of retractions may be due to better error-spotting, because the Internet and software advancements have led to more sharing and better analysis. Also, insiders point to a shift in research culture as pressure mounts for researchers to publish in order to advance their careers and attract increasingly scarce funding for further research.

Damage control

Once an error or fraud is detected in research, the correct approach calls for a swift and thorough investigation to clean up the medical literature by forcing a retraction of the incorrect information and identifying any intentional misconduct. Yet the process is usually quite slow, and it seems to take longer to retract a paper for wrongdoing than for an innocent mistake: The 2010 paper by Steen found that it took an average of 28.4 months after publication to retract a paper for fraud, while it took an average of 22.9 months to retract for error.

When it comes to fixing the problems created when an article with erroneous information slips through the review process, academic journals are not always cooperative. Frequently slow to investigate or issue a retraction when concerns are raised, journals often rely on the individual researcher or research institution to contact them with

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retraction statements.

Sometimes retractions are issued with little explanation and state only that the article was “withdrawn at the request of the authors.” Editors can be reluctant to say more. When reporters from the blog Retraction Watch contacted editor L. Henry Edmunds of *The Annals of Thoracic Surgery* to ask about a paper withdrawn from the journal, his now-infamous reply was, “It’s none of your damn business!”

Ensuring reliability

Addressing the problem of scientific fraud will require a change in the cultural norms for how a responsible journal editor responds to questionable articles, as well as a lot more work on editors’ lists of tasks.

Even well-meaning journal editors have difficulty keeping up with their duties, especially because many editors are scientists or physicians working on a voluntary basis. But it is work that must be done, as Dr. Nicholas Steneck, a research ethicist from the University of Michigan in Ann Arbor told *Nature* last October: “If you don’t have enough time to do a reasonable job of ensuring the integrity of your journal, do you deserve to be in business as a journal publisher?”

Institutions have an obligation to ensure the integrity of the research being conducted under their authority. Yet in some ways, institutions are poorly situated to police themselves because the institutional review boards charged with approving and monitoring research are also staffed with overworked volunteers. Investigations can be time-consuming: The University of Connecticut investigation of Das’ work produced a report that was 60,000 pages long. Faculty may also be reluctant to question research done by a colleague at their institution.

It adds accountability when outside

funders get involved. When allegations of error began to surface around Potti’s cancer research, Duke University failed to launch an investigation until concerns were raised by the National Cancer Institute (NCI), a government body that had agreed to fund Potti’s research. Duke hired an external review committee to review the work of Potti and his colleagues. Yet even this effort was not enough. The review committee was provided only with material supplied by the researchers themselves and did not have access to NCI’s exact concerns or other criticisms raised by independent researchers who had attempted to replicate the work.

Ultimately, a solution to the problem may require an entirely new framework for reviewing medical research, one that relies less heavily on voluntary efforts by interested parties. An existing government agency involved in policing research misconduct, the Office of Research Integrity (ORI) at the Department of Health and Human Services, could play a useful role. The ORI has been active in detecting fraud and notifying the public. In August 2011, the agency’s investigators concluded that a Boston University cancer researcher had fabricated data in two published papers.

Combating scientific fraud should include a multifaceted approach involving swift-acting journal editors, engaged research institutions, vigilant researchers and outside funders. An even more effective plan would bring in a fully funded federal agency with oversight of all research conducted at federally funded institutions or conducted for the purpose of FDA approval (a plan that would probably require an act of Congress to implement). The credibility of scientific research is not the only item at stake. Patient health also hangs in the balance. ♦

Chronic Fatigue Syndrome

A Mystery Disease

No one knows for sure exactly what chronic fatigue syndrome (CFS) is, what causes it or how to treat it. The Centers for Disease Control and Prevention (CDC) defines CFS as having “severe chronic fatigue for at least 6 months or longer that is not relieved by rest and not due to medical or psychiatric conditions associated with fatigue.” The CDC requires patients to have four out of eight possible symptoms: memory problems, recurrent sore throat, tender lymph nodes, muscle pain, multi-joint pain, headaches, unrefreshing sleep and post-exertional malaise lasting more than 24 hours.

Understandably, those who suffer in these ways would desperately like to have a cause discovered, along with a cure. Over the last 30 years or so, a multitude of groups have arisen, particularly in the U.S. and the U.K., to do just that.

In the 1950s, the syndrome was identified in Britain, where CFS is known as myalgic encephalomyelitis (ME), implying brain and spinal cord inflammation with muscle pain (even though no proof exists that such inflammations occur). In the U.S., it was identified in the 1980s as CFS and is often referred to as CFS/ME in research circles.

Though little solid information exists about the syndrome, there are reams of CFS-related material on multiple health websites (including those of the Mayo Clinic, the CDC and the National Institutes of Health, as well as those of at least a dozen private groups and organizations).

Researching the cause: false alarm

Researchers saw no real progress on finding a cause until October 2009, when researchers at a private research institute in Nevada published a paper in the prestigious journal *Science* that claimed to have identified a virus in the

The Centers for Disease Control and Prevention (CDC) defines [Chronic Fatigue Syndrome] as having “severe chronic fatigue for at least 6 months or longer that is not relieved by rest and not due to medical or psychiatric conditions associated with fatigue.”

blood of CFS patients but not in that of healthy control subjects. It was novel: xenotropic murine leukemia virus-related virus (XMRV).

The discovery provided much excitement in the scientific community and much relief in those affected. Now CFS patients would be vindicated in showing the world that they really did have a medical reason for their illness and would now have potential cures available.

The excitement and relief did not last long. Because the original finding promised such a breakthrough, many groups took up the challenge to try and replicate it, a time-honored response to new findings such as this. A paper published in January 2010, only three months later, titled “Failure to Detect the Novel Retrovirus XMRV in Chronic Fatigue Syndrome,” reflected an inability to replicate the original results. Many similar papers have followed.

Another paper showed that the virus was a contaminant introduced in the original study, and other research showed that the virus was not a genuine human pathogen but an artifact of a combination of two viruses.

In July 2011, as more contradictory information continued to surface, the editors of *Science* asked the authors of the 2009 paper to retract it. When the researchers refused, the *Science* editor-in-chief published an “Editorial Expression of Concern.”

The paper was later partially retracted in September and fully retracted in December 2011. Yet one of the researchers has not given up the hypothesis.

A mental or physical condition?

Another CFS controversy concerns suggestions by some researchers and physicians that symptoms of the syndrome might not have a physical basis. CFS has thus become an emotional issue for those suffering it, and they are willing to do battle with anyone proposing a mental rather than a physical cause.

Patients are especially furious with those medical professionals who would suggest that CFS might be due to physical inactivity, anxiety or depression. Because of his writings on this subject, Dr. Simon Wessely, a professor of epidemiology and psychiatry at King’s College London School of Medicine, has been a target of CFS patients, even enduring threats to his life. As a consequence, he has abandoned the field of CFS and now works with war veterans.

Dr. Charles Shepherd, a medical adviser and trustee of the U.K. association committed to helping CFS sufferers, also has been a victim of attacks because he voiced skepticism about the claims that XMRV is responsible for CFS. After slanderous website posts about him, he also has begun to consult with the police.

Controversy over cognitive behavior therapy solutions

Much of the patients’ anger is a reaction to studies showing that therapy involving psychiatric and behavioral elements helps CFS patients.

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The Cochrane Collaboration, in July 2008, published an analysis of randomized controlled trials on CFS. These authors concluded that cognitive behavior therapy (CBT, a type of psychotherapy) was significantly more helpful than usual care (such as rest, less activity, antidepressants and general support) in relieving symptoms of CFS, although they felt that further studies would be useful.

Continuing in this line of research, a study published in the March 2011 issue of the medical journal *Lancet*, focusing on the PACE (Pacing, Graded Activity and Cognitive Behavior Therapy) trial, has caused great anger in some in the

CFS community. The PACE trial concluded that graded exercise therapy and CBT were useful in CFS treatment, whereas adaptive pacing therapy (APT) was not.

This contradicted many CFS practitioners, who advocate APT as the basis of much of the CFS treatment regimen. APT, according to the *British Medical Journal*, “involves achieving the correct balance between rest and activity and establishing a routine to be carried out on both good and bad days.” An emeritus professor of medicinal chemistry penned a 442-page response to the Medical Research Council, one of the funders of the PACE trial, and a 43-page rebuttal to the *Lancet*. The professor branded the trial “unethical

and unscientific” and stated data had been manipulated.

A journalist writing on CFS in the *British Medical Journal* in June 2011 concluded that “[a]ll of those who approach CFS/ME from a psychiatric perspective are the targets of critics who believe the disease has a physical cause,” reflecting the school of thought that the cause of the disease could be resolved if not for psychiatrists who press the case of a mental, not physical, cause for CFS. It seems to be a sad commentary on our times that scientific information, such as the research on a physical cause for CFS, is treated as something that stands in the way of progress rather than a path to a useful solution. ♦

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manufacturers and users of medical devices, such as hospitals, to report incidents of serious injuries or deaths related to the use of medical devices. Manufacturers, in turn, are often unable to locate patients implanted with dangerous devices because there is no adequate system tracking which patients have received their products.

The FDA also has been criticized for making poor use of the data it does receive from device manufacturers concerning recalled products. The government regulator lacks an internal system to analyze recall trends, which it might otherwise use in future decisions when reviewing a device for approval under the PMA process or clearance under the 510(k) process.

Public Citizen's recommendations to improve medical device safety

The statistics on rising recalls and the many tragic case studies of people seriously harmed by medical devices clearly demonstrate the dangers and weaknesses of the existing systems for both premarket review and post-market surveillance of medical devices. Premarket regulation of devices has

In just the third and fourth quarters of 2011, at least 225 industry lobbyists ... lobbied members of Congress or executive branch officials on issues relating to medical device regulation.

repeatedly failed to prevent unsafe devices from reaching the market and injuring and killing patients.

Further, devices unequivocally shown to be unsafe after receiving permission to be marketed have not been removed from the market in a timely manner by the FDA. Congress and the FDA need to strengthen applicable statutes and policies for reviewing and monitoring devices. (Table 3 on page 3 lists Public Citizen's key recommendations for improving medical device safety.)

In particular, Public Citizen calls on Congress to replace the current medical device clearance and approval processes with a process that requires the same scrutiny as that given to new drugs, particularly for moderate- and high-risk medical devices that are permanently

implanted in the body, life-sustaining or life-supporting.

In the interim, Congress and the FDA should require additional safeguards for devices cleared under the current 510(k) process, more rigorous clinical trials for devices being considered for approval under the PMA process, stricter reporting of adverse events, the maintenance and analysis of a database of device recalls ensuring that they are implemented effectively, and improved tracking of patients receiving medical devices.

Finally, Congress should restore patients' legal rights to sue device manufacturers for harm resulting from defective devices. Given the 2008 U.S. Supreme Court ruling stating that manufacturers of most PMA-approved devices cannot be held liable for harms, these rights could not come sooner.

To read the entire Public Citizen report, visit www.citizen.org/substantially-unsafe-medical-device-report. ♦

Product Recalls

February 2, 2012 – February 29, 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), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Excedrin Tension Headache Caplets (acetaminophen, 500 mg; caffeine, 65 mg), a) 100 count, b) 125 count and c) 250 count. Volume of product in commerce: 1,186,332 bottles. Adulterated presence of foreign tablets: Consumer complaints of foreign tablets reported in

the products. Lot #s: a) 10087530, expiration date 03/31/2013; b) 10089902, expiration date 04/30/2013; and c) 10063947, expiration date 11/30/2011. Novartis Consumer Health.

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

Assured Pain Relief for Arthritis Caplets (acetaminophen), 650 mg, 24 count. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: Multiple lots affected. Contact your pharmacist. Advance Pharmaceutical Inc.

commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Azithromycin, 250-mg tablets, one card, six tablets. Volume of product in commerce: 720 boxes. Labeling: Label with incorrect expiration date. Lot #: 1318262, expiration date 04/2014. Teva Pharmaceutical Industries.

Consumer's Choice Pain Relief for Arthritis (acetaminophen), 650-mg caplets, 24 and 100 count. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: Multiple lots affected. Contact your pharmacist. Advance Pharmaceutical Inc.

Bufferin Buffered Aspirin Low-Dose Coated Tablets (aspirin buffered with calcium carbonate, magnesium carbonate and magnesium oxide), 81 mg, 130 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

DynaCirc CR Tablets (isradipine, controlled release), 5 and 10 mg, 30 count. Volume of product in commerce: 394,230 bottles. CGMP deviations: These lots are being recalled due to compliance concerns regarding the level of CGMP compliance and procedural controls related to line clearance during the packaging process at the Novartis Consumer Health site. Lot #s: Multiple lots affected. Contact your pharmacist. Novartis Consumer Health / Patheon Pharmaceuticals Inc.

Bufferin Extra-Strength Buffered Aspirin Coated Tablets (aspirin buffered with calcium carbonate, magnesium carbonate and magnesium oxide), 500 mg, 39 and 130 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Back and Body Extra-Strength Bi-Layer Caplets (acetaminophen, 250 mg; aspirin, 250 mg, buffered with calcium carbonate), 24, 50 and 100 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Bufferin Regular-Strength Buffered Aspirin Coated Tablets (aspirin buffered with calcium carbonate, magnesium carbonate and magnesium oxide), 325 mg, 130 count. Volume of product in

Excedrin Extra-Strength Caplets (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 24, 30 (24 + 6 bonus), 50, 100, 125 (100 + 25 bonus), 250 and 300 (250 + 50 bonus) count. Volume of product

in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Extra-Strength Express Gels Gelcaps (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 20, 40 and 80 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Extra-Strength Geltabs (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 24 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Extra-Strength Tablets (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 8, 24, 30 (24 + 6 bonus), 50, 100, 125 (100 + 25 bonus), 200, 250, 300 (250 + 50 bonus) and 300 count; and 300-count club pack (three 100-count bottles). Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Menstrual Complete Express Gels Gelcaps (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 20 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Migraine Caplets (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 8, 24, 30 (24 + 6 bonus), 50, 100, 125 (100 + 25 bonus), 200, 250 (200 + 50 bonus), 250 and 300 count; and 300-count club pack (three 100-count bottles). Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Migraine Geltabs (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 24, 50, 100 (twin pack carton: two 50-count bottles) and 160 (twin pack carton: two 80-count bottles) count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Migraine Tablets (acetaminophen, 250 mg; aspirin, 250 mg; caffeine, 65 mg), 24, 30 (24 + 6 bonus), 50, 100, 125 (100 + 25 bonus) and 250 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin PM Caplets (acetaminophen, 500 mg; diphenhydramine citrate, 38 mg), 24, 50, 100 and 125 (100 + 25 bonus). Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin PM Express Gels Gelcaps (acetaminophen, 500 mg; diphenhydramine citrate, 38 mg), 20 and 80 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin PM Tablets (acetaminophen, 500 mg; diphenhydramine citrate, 38 mg), 8, 24, 30 (24 + 6), 50, 100 and 125 (100 + 25 bonus) count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Sinus Headache Caplets (acetaminophen, 325 mg; phenylephrine hydrochloride, 5 mg), 24 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Tension Headache Caplets (acetaminophen, 500 mg; caffeine, 65 mg), 24, 30 (24 + 6 bonus), 50, 100, 125 (100 + 25 bonus) and 250 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Excedrin Tension Headache Express Gels Gelcaps (acetaminophen, 500 mg; caffeine, 65 mg), 20, 40, 80 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Excedrin Tension Headache Geltabs (acetaminophen, 500 mg; caffeine, 65 mg), 24 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Gas-X Prevention Capsules (alpha-galactosidase enzyme), 600 GALU, 20 and 50 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Lo/Ovral-28, 21 white tablets, each containing 0.3 mg norgestrel with 0.03 mg ethinyl estradiol, and seven pink, inert tablets. Package contains six Pilpak dispensers of 28 tablets each. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Some blister packs may contain an inexact count of inert or active-ingredient tablets, and the tablets may be out of sequence. Lot #s: Multiple lots affected. Contact your pharmacist. Pfizer Inc.

Maximum-Strength NoDoz Coated Caplets (caffeine), 200 mg; 16, 36 and 60 count. Volume of product in commerce: Unknown. CGMP deviations: Potential for the bottles to contain foreign tablets or broken/chipped tablets. Lack of CGMPs. Lot #s: All lots that bear the expiration date of 12/20/2013 or earlier and all lots that bear the expiration date of 12/20/2014 or earlier. Novartis Consumer Health.

Norgestrel 0.3 mg / Ethinyl Estradiol 0.03 mg Tablets, 21 white tablets, each containing 0.3 mg norgestrel with 0.03 mg ethinyl estradiol, and seven pink, inert tablets. Package contains six Pilpak dispensers of 28 tablets each. Volume of product in commerce: Unknown. Contraceptive tablets out of sequence: Some blister packs may contain an inexact count of inert or active-ingredient tablets, and the tablets may be out of sequence. Lot #s: Multiple lots affected. Contact your pharmacist. Pfizer Inc.

Preferred Plus Acetaminophen for Arthritis (acetaminophen), 650 mg, 100 caplets. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect

dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: Multiple lots affected. Contact your pharmacist. Advance Pharmaceutical Inc.

Premier Value Arthritis Pain Relief Caplets (acetaminophen), 650 mg, 50 and 100 count. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: All lots. Advance Pharmaceutical Inc.

Quality Choice Arthritis Pain Relief Caplets (acetaminophen), 650 mg, 50 and 100 count. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: Multiple lots affected. Contact your pharmacist. Advance Pharmaceutical Inc.

Select Brand Arthritis Pain Relief Caplets (acetaminophen), 650 mg; 24, 50 and 100 count. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: The recall is due to incorrect dosage information indicated on the primary bottle and the outside carton labeling. The labeling contained the following information: Take two caplets every eight hours with water. This labeling exceeds the allowable monograph quantity of acetaminophen in an eight-hour period. Lot #s: Multiple lots affected. Contact your pharmacist. Advance Pharmaceutical Inc.

Topiramate Tablets, 25 mg, a) 1,000 count and b) 60 count. Volume of product in commerce: 82,653. Impurities/degradation products: High OOS results for impurity. Lot #s: a) 28T027, expiration date 01/2012; b) 28T030, expiration date 01/2012, and 16T020, expiration date 01/2012. Teva Pharmaceutical Industries Ltd.

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

Adjustable Ottoman Bed. When the ottoman is converted into a bed and weight is put on it, it can collapse, posing a fall hazard to consumers. JN Bailey and Associates Inc., at (800) 985-6044 or www.improvementscatalog.com.

All-Terrain Vehicle (ATV). A weld on the ATV's front right, upper suspension arm can separate, causing the driver to lose control of the

vehicle and posing a crash hazard. American Honda Motor Co., at (866) 784-1870 or powersports.honda.com.

Children's Pajamas and Sleepwear. The garments fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injury to children. Papa Bear Loungeabouts LLC, at 866-472-5262 or www.pajamamania.com.

CONSUMER PRODUCTS (continued)

Crystal Chandeliers. The recalled chandeliers contain a mounting loop that can fail during use, causing the chandeliers to fall from the ceiling and injure bystanders under them. Spectrum Home Furnishings, at (800) 524-1539 or www.spectrumhome3.com.

Dancing Teapots. The teapot's handle can get extremely hot when there is hot water in the teapot, posing a burn hazard to consumers. Ganz U.S.A. LLC, at (800) 724-5902 or cpsr-rspc.hc-sc.gc.ca/PR-RP/recall-retrait-eng.jsp?re_id=1527.

Fire Alarm Control Panel. On all systems, when the alarm verification feature of the system is turned on, the control panel can fail to sound an alarm if a fire occurs. In addition, on systems with 50 or more reporting stations, a delay in sounding an alarm and reporting a fire may occur if the loop for the alarm system is broken. Bosch Security Systems Inc., at (800) 289-0096 or www.boschsecurity.us/en-us/.

Folding Pocket Utility Knife. The blade-locking mechanism can fail, allowing the blade to fold inward toward the handle and posing a laceration hazard. Greenlee Textron Inc., at (800) 435-0786 or www.greenlee.com.

FoodService Beverage Cups and Mugs. The cups and mugs can break when exposed to hot liquids, posing a burn hazard to consumers. Carlisle FoodService Products, at (800) 217-8859 or www.carlislefsp.com/productsafety.

Forced Air Heater. Exposed and unshielded electrical components can cause the heater to overheat and melt, posing fire and electrical shock hazards. Meijer Inc., at (800) 927-8699 or www.meijer.com.

Fuji Saratoga Women's Bicycles. The bicycle's frame can break in the center of the down-tube during use, causing the rider to lose control and fall. Advanced Sports Inc., at (888) 286-6263 or www.fujibikes.com.

Gas-Powered Backpack Blower. The fuel line between the fuel tank and carburetor could have been damaged during assembly, which can lead to fuel leakage and pose a fire hazard. ECHO Inc., at (800) 432-3246 or www.echo-usa.com.

Grass Trimmers. The shaft can crack and cause the lower gear case and cutting attachment to detach, posing a laceration hazard to the operator and bystanders. American Honda Motor Co., at (888) 888-3139 or powerequipment.honda.com.

GSM Radio Modules Used in Go! Control Panels. The modules can overheat and combust, resulting in a fire or burn hazard to consumers. 2GIG Technologies Inc., at (855) 244-4832 or www.2gig.com.

Kelty Single and Double Jogging Strollers. The front wheel can come loose during use and cause the stroller to tip over, posing a fall and injury hazard to children in the stroller and adults pushing the stroller. Kelty, a division of American Recreation Products, at (866) 349-7225 or www.kelty.com.

Latch for Utility Vehicle Door. The latch pin can disengage from the latch, allowing the door to open while the vehicle is moving. This can pose a risk of ejection for an unrestrained rider as well as impact or laceration hazards. LSI Products Inc. dba Pro Armor, at (888) 312-7667 or www.proarmor.com.

Living Traditions 21-Inch Rooster Lamps. The electrical cord can fray near the base of the lamp, posing a fire or shock hazard to consumers. Designs Direct, at (888) 770-7062 or www.regcen.com/roosterlamp.

Map Pro, Propylene and MAPP Gas Cylinders. The seal on the cylinders can leak after torches or other fuel consuming equipment are disconnected from them, posing a fire hazard. Worthington Cylinders Wisconsin LLC, at (866) 511-8967 or www.MAPCylinderRecall.com.

Mountain Bicycle Handlebar Stem. The bolts holding the front plate of the stem to the stem body can be pulled out of the threads while the bike is being ridden, causing the rider to lose control of the bike and fall. Shimano American Corp., at (800) 353-4719 or www.shimano.com.

MS 391 Chain Saws. The flywheel on the chain saw can crack, causing parts of the flywheel to separate and strike users or bystanders and posing a risk of injury. STIHL Inc., at (800) 610-6677 or www.stihlusa.com.

Slalom Glider. The playground slide lacks a transition platform on the top and sides of the chute. Children can fall when moving from the ladder to the slide and when descending the chute. Landscape Structures Inc., at (888) 438-6574 or www.playlsi.com.

SolarBlend Roof Tiles. The connectors between the solar roof tiles can become loose, posing a fire hazard. Wuxi Suntech Power Co. Ltd., at (888) 770-7122 or www.suntech-power.com/product-safety.

Standard and Economy Hammock Stands. The foot brackets used to support the hammock can crack, causing the stand to collapse. This poses a fall hazard to consumers. Twin Oaks, at (800) 688-8946 or www.twinoakshammocks.com.

Tassimo Espresso T Discs. The recalled espresso T Discs can become clogged and spray hot liquid and coffee grounds onto consumers and bystanders during or after brewing, posing a burn hazard. Kraft Foods Global Inc., at (866) 918-8763 or www.tassimodirect.com/safetyrecall.

Tassimo Single-Cup Brewers. The plastic disc, or T Disc, that holds the coffee or tea can burst and spray hot liquid and coffee grounds or tea leaves onto consumers and bystanders, posing a burn hazard. BSH Home Appliances Corp., at (866) 918-8763 or www.tassimodirect.com/safetyrecall.

Tumblekins Toys. The toys can break into small pieces with sharp points, posing choking and laceration hazards to children. Lishui Tree-toys Trading Co. Ltd., at (800) 445-8347 or recall@intplay.com.

Outrage of the Month! Treating Sick Rich Folks

This month's Outrage column was written by Public Citizen board member Jim Hightower and appears with his permission.

In these trying times of health care austerity, it reaffirms one's faith in humanity to learn that many hospitals are now going the extra mile to provide top quality care for all.

For all super-rich people that is. These folks are so rich they can buy their way into "amenities units" built into secluded sections of many hospitals. It's not medical care that they're peddling to an elite clientele, but the personal pampering that the super-rich expect in all aspects of their lives.

"I was supposed to be in Buenos Aires last week taking tango lessons," a Wall Street executive explained matter-of-factly to a *New York Times* reporter, "but unfortunately, I hurt my back, so I'm here with my concierge."

A hospital with a concierge? Yes. There's one called Eleven West, an exclusive wing of New York's Mount Sinai Medical Center. "We pride ourselves on getting anything the patient wants," beamed its director of hospitality. "If they have a craving for lobster tails and we don't have them on

the menu, we'll go out and get them."

From New York to Los Angeles, hospitals that draw huge subsidies from taxpayers (and often are so overcrowded that regular patients are lucky to get a gurney in the hallway) have set aside entire floors for \$2,400-a-day deluxe suites. They come with butlers, five-star meals, marble baths, imported bed sheets, special kitchens and other amenities for swells who have both insurance and cash to burn.

It's repugnant for the plutocratic elite to pervert health care into a luxury commodity. It splits asunder America's essential, uniting principle of the common good.

To push for a national policy that treats health care as a fundamental human need — for all — contact Physicians for a National Health Program: www.pnhp.org.

Jim Hightower is also a radio commentator, writer and public speaker and is editor of the populist newsletter Hightower Lowdown.

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