



States in the Spotlight as Single-Payer Resurfaces in Mainstream Discourse

The past year has seen single-payer health care in the news more than usual. May marks the first anniversary of Vermont’s health reform bill, which was widely touted as the first state single-payer law in the country — albeit only by those who had presumably not read the bill. Following closely on the heels of the Vermont law was one of the most high-profile U.S. Supreme Court cases in decades. The Obama administration’s controversial 2010 health reform law, the Affordable Care Act (ACA), came before the Supreme Court this March over a challenge to its constitutionality.

Both Vermont’s law and the court hearings have put a renewed spotlight in establishment circles on single-payer. The mainstream press usually focuses on single-payer only to ridicule it as a fringe cause lacking “political will” (a revealing term, given that a majority of the public has long supported a national health insurance system along the lines of single-payer), and this has largely remained the case in the current debate. But the possible repeal of the ACA, combined with efforts by many states to opt out of the reform, has led many who were formerly enamored with the ACA to ask what’s next and has forced a surprisingly frank discussion of the possibilities and merits of a U.S. single-payer health care system.

Saskatchewan’s example and Obama’s obstructionism

With just over 1 million residents, the sparsely populated Canadian province of Saskatchewan is not

Fast-forward half a century, and Canada’s southern neighbor has yet to enshrine health care as a right instead of a privilege that remains out of reach for 50 million uninsured Americans.

often in the headlines. But 50 years ago, the rural province was a staging ground for one of the most significant social justice achievements of the last century. The province’s pioneering, publicly financed health insurance system, first enacted for hospital care in the aftermath of World War II and gradually built upon over the next two decades, guaranteed medical coverage to all residents regardless of income and laid the groundwork for Canada’s single-payer health care system.

This milestone did not come without resistance from entrenched interests, most notably the province’s medical community. In a prelude to the American Medical Association’s opposition to Medicare a few years later, Saskatchewan’s physicians staged a 23-day strike in 1962 to protest the plan, which they thought would weaken their socially privileged positions within the health care system and, especially, their inflated salaries. In the end, the provincial government won (though not before agreeing to keep the physician-friendly, costly fee-for-service payment arrangement), and the success of its system led to universal health insurance in Canada within 10 years.

Fast-forward half a century, and Canada’s southern neighbor has yet to enshrine health care as a right instead

of a privilege that remains out of reach for 50 million uninsured Americans. While Tommy Douglas, the man most responsible for bringing national health insurance to Canada, is feted as a hero, in the U.S., even tepid movements to increase health care access have met with extreme hostility from corporate interests. Despite the Obama administration’s best efforts to portray the 2010 ACA as a step toward universal health care, the law actually further entrenches the private insurance industry at the heart of the health care system, while leaving 27 million uninsured and tens of millions more underinsured when fully implemented.

A government-financed national health insurance system would, as noted by most commentators across the political spectrum, achieve the

see **SINGLE-PAYER**, page 2

In This Issue

Wide Variation in Rates of Second Breast Cancer Surgery.....	4
Nondrug Treatments for Neck Pain Better Than Medications.....	6
RECALLS.....	10
OUTRAGE!.....	12

PUBLIC CITIZEN
Health Letter

MAY 2012
Vol. 28, No. 5

Editor

Sidney M. Wolfe, M.D.

Managing Editor

Cynthia Williams

Contributors

Sidney M. Wolfe, M.D.
Sammy Almashat, M.D., M.P.H.
Michael A. Carome, M.D.
Sarah Sorscher, J.D., M.P.H.

Graphic Designer

Erin Hyland

Public Citizen President

Robert Weissman

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C., to fight for the public's health and give consumers more control over decisions that affect their health.

Annual subscription rate is
\$18.00 (12 issues).

Material in the *Health Letter* may not be reprinted without permission from the editor. Send subscription requests and address changes to:

Health Letter

1600 20th St. NW
Washington, DC 20009

Copyright © *Health Letter*, 2012
Published monthly by Public Citizen's
Health Research Group
All rights reserved. ISSN 0882-598X

SINGLE-PAYER, from page 1

purported goal of an individual mandate — universal coverage — while being unquestionably constitutional. Justice Anthony M. Kennedy (widely seen as the swing vote in this summer's decision on the ACA) most notably articulated this point when he observed during the Supreme Court hearings that the government could simply “use the tax power to raise revenue and to just have a national health service, single payer.”

A simple option in theory, perhaps, but one that was unacceptable to the Obama administration. President Barack Obama systematically excluded the single-payer option from consideration early in the process, ignoring high-profile protests from organizations such as Physicians for a National Health Program and Healthcare-NOW. With his approval ratings at their peak and a Democratic Congress at his back, Obama chose not to put single-payer on the table — though he acknowledged it as the only way to cover all Americans and there was majority support for single-payer among the American public.

**Vermont's misleading
2011 law: single-payer
in name only**

Single-payer activists were not deterred by the subsequent gift to the private insurance industry that was the core of the ACA, instead turning their efforts to the states, with Saskatchewan's precedent in mind.

Vermont was the first battleground for single-payer following the ACA, and it seemed an ideal place to focus the movement's efforts. The state is decidedly progressive and has a long history of implementing progressive health legislation, such as a pre-ACA prohibition on denial of coverage for pre-existing conditions, a generous Medicaid system and a more recent ban on gifts from pharmaceutical manufacturers to physicians. In 2010, the election of a new governor, Peter Shumlin, committed in principle to

single-payer, raised expectations that Vermont might be the successful laboratory from which to build a national “Improved Medicare for All” system.

When Shumlin was still in the Vermont Senate, local single-payer advocates such as Deb Richter put him in contact with William Hsiao, the Harvard economist who designed Taiwan's single-payer system in the 1990s. Following Shumlin's election as governor, the state formally enlisted Hsiao to design a health care system that would accomplish three overarching goals: 1) universal coverage with sufficient benefits, 2) an equitable financing mechanism yielding long-term cost savings and 3) a more integrated delivery system focused on prevention and primary care.

Hsiao's team presented three options to the state legislature in 2011, only the first of which was a true single-payer system. The latter two would still allow multiple private insurance payers to operate. In its report, the team recommended a so-called “public/private” non-single-payer option as the “most feasible because it is likely to be accepted by the broadest cross-section of stakeholders in Vermont.”

The most powerful stakeholders were undoubtedly the state's private insurers, who had no desire to go quietly into the night as their Canadian predecessors had done 40 years ago. The insurers, including the largest, Blue Cross/Blue Shield (BCBS), positioned themselves firmly against the true single-payer option.

The opposition was subtle: BCBS presented itself to the public as a neutral observer, while by its own admission it worked behind the scenes to water down the bill as much as possible. As Leigh Tofferi of BCBS put it, “[W]e didn't oppose it” but “wanted to make sure it was worded so as to be workable.” The company's support of the final bill was explained in Tofferi's brazen statement that “if there's a single-payer system,

see SINGLE-PAYER, page 3

SINGLE-PAYER, from page 2

we'd like to be the single payer.”

The Vermont Chamber of Commerce, meanwhile, lobbied against enacting any substantial reform until health care costs could be brought under control through various business-friendly solutions — a catch-22 because any serious cost controls would require the kinds of reforms the Chamber opposed.

In the face of this opposition, the state adopted Hsiao's public/private non-single-payer option as Act 48 in May 2011. The new law's stated mission was to ensure “universal access to and coverage for high-quality, medically necessary health services for all Vermonters.”

However, much of the plan is more a mission statement than a tangible reform of the existing system. The core of the plan aims to gradually merge existing payers (for example, insurers) into a single “independently” administered payer, Green Mountain Care. But this central provision depends on new legislation and a federal waiver and, even if successful, would not be fully implemented until three to five years from now.

Although service through Green Mountain Care will be paid for with public funds, it will not be administered by the government but by representatives from existing payers and beneficiaries, such as employers, the state government and consumers. The plan will not be universal — initially incorporating only plans represented in the ACA-mandated state health insurance exchange in 2014, such as Medicaid and, possibly, the individual and small-group private insurance markets — and will exclude Medicare beneficiaries, state employees and school employees. The Vermont system will also contract out to private insurers' tasks such as claims administration and other services.

The bill does contain some good provisions. For one, all Vermont residents (except undocumented immigrants, whose eligibility will be determined at a later date) would be

State alternatives to the Affordable Care Act (ACA)

Although Vermont emphasized its intent to build upon the 2010 federal health reform bill to move toward single-payer, the details of the law have proven a major obstacle to that goal. The ACA allows a state to opt out of the law if the state creates an alternative plan that would cover as many people, with similar benefits, at the same cost as the federal law. However, states cannot even apply for such a waiver until 2017. Vermont and other states are lobbying for an earlier, 2014, waiver, but the window is steadily closing on this possibility.

eligible, insurance status would not be linked with employment, prevention and primary care would be prioritized and more efficient payment methods would be promoted to replace the inflationary fee-for-service model, which rewards higher and more expensive health care utilization.

More importantly, however, the plan's weaknesses go to the core of the legislation. The failure to enact a single-payer system may prove decisive in preventing the plan's survival, because it relies on long-term cost savings. The presence of multiple payers would prevent the system from realizing the vast administrative savings that would immediately come from a true single-payer system. The continued operation of private insurers, in particular, will undermine the law's intent to create an equitable system. Private companies will be allowed to provide supplemental insurance to those able to afford it, thus creating a two-tier system based on wealth — precisely what single-payer is designed to avoid. The contracting out of tasks such as claims processing to these same insurers will undoubtedly add additional expenses.

The lack of a single payer with centralized claims processing may also prevent the state from achieving Canada's and Medicare's successes in creating comprehensive databases on health outcomes. Canada's single-payer system has allowed provinces such as Ontario and British Columbia to track data on interventions and health outcomes for every resident. This tracking has facilitated an enormous amount of vital research. More importantly for Vermont, such data would have also enabled the state to evaluate whether the new system improved care for the state's residents over time, one of the goals of the law.

Whatever the cost, there is, as yet, no plan to pay for the new system. If funded at all, the most likely outcome would be a flat payroll tax on employers and employees on the first \$106,800 of income, replicating the regressive Social Security tax.

Other states take tentative steps

Vermont is obviously unique both politically and, with a population of only around 600,000 residents in the state, demographically. Even its partially successful example cannot be readily applied to other states.

However, the common perception that single-payer is more possible in Democratic states is too simplistic. The real dichotomy is between Republican and Democratic leaders on one side, backed by the same financial interests, and the majority of the public on the other. Medicare's overwhelming popularity contrasts sharply with the unpopularity of private insurance companies and makes a single-payer option possible across the political spectrum, even one narrowly defined in partisan terms.

Framed this way, even Republican state officials have espoused single-payer as a policy option, with the Republican attorney general of Louisiana recently calling for a single-payer model nationwide and telling the

[see SINGLE-PAYER, page 9](#)

Wide Variation in Rates of Second Breast Cancer Surgery

Researchers Call for Clearer Standards

A study that was published in the Feb. 1, 2012, *Journal of the American Medical Association (JAMA)* found that among individual surgeons and hospitals, there was wide variation in the rates for a second operation after initial breast cancer conservation surgery in women. The variation suggests that some repeat surgeries may be unnecessary and, conversely, that some necessary second surgeries may not be performed. This inconsistency, the study's authors argue, may result from disagreement among surgeons about when a second operation is appropriate.

JAMA study overview

The study focused on 2,206 women who had undergone breast conservation surgery at one of four hospitals around the U.S. Breast conservation surgery, also called a lumpectomy or partial mastectomy, aims to remove the cancer tumor and enough of the surrounding tissue to be certain that no cancer cells were left behind and to maintain the cosmetic appearance of the breast. The surgery serves as an alternative to a complete mastectomy, in which the entire breast is removed.

Of the 2,206 women in the study, 23 percent of those who were initially considered good candidates for breast conservation surgery underwent additional surgery on the same breast after their initial lumpectomy. Surgeons varied widely in their rates of performing these surgeries, from none for some surgeons to 70 percent for others. The rates of second surgeries also varied widely among hospitals, from 2 to 21 percent. Yet the decision whether to perform a second surgery was not based entirely on the clinical evidence recorded in the study (including tumor size, cancer type and the margin of healthy tissue initially removed along with the tumor).

Instead, the patterns of practice associated with an individual hospital or operating physician, rather than patient-specific factors, emerged as key indicators predicting whether a patient would undergo a second surgery. This means that based on which doctor or hospital she visits, the same patient may get very different advice about whether to have a second surgery.

"That is probably not what we would like to see," said Dr. Laurence E. McCahill, the lead author of the study and director of surgical oncology at the Lacks Cancer Center in Grand Rapids, Mich. McCahill believes that better guidelines for interpreting surgery results can help to ensure consistent care across the U.S.

Disagreement on how to interpret results of breast conservation surgery

During breast conservation surgery, doctors remove a lump of cancerous tissue, along with some of the surrounding healthy tissue, from the breast. Optimally, surgeons like to see a margin of healthy tissue completely surrounding the cancer cells in the lump they have excised in order to be sure that all of the cancer was removed. To check that margin, the removed tissue is rolled in ink and observed under a microscope. Physicians can then see how big a margin of healthy tissue exists between the cancer cells and the inked edge.

A "negative" or "clean" margin means healthy tissue lies between the tumor and the inked edge. A "positive" margin signals that the cancer cells are touching the inked edge and, therefore, that some cancer cells were left behind.

Strong evidence demonstrates that a cancer is more likely to return in the same place after a surgery that resulted in a positive margin versus a negative or

clean margin. Surgeons generally agree that finding a positive margin requires a second operation.

Yet physicians have not reached consensus on how thick an acceptable negative margin should be. Some surgeons do not see a need for a second operation as long as the cancer cells do not touch the inked edge. Others recommend a second surgery unless the negative margin is 1 to 2 millimeters (mm) thick, and a few doctors demand a centimeter (10 mm) or more of healthy tissue to ensure that no cancer cells were left behind.

The reason for this disagreement is that no one has ever carried out a well-designed study to test the effects of negative margin width on rates of cancer recurrence or long-term survival.

The lack of consensus among doctors means that some physicians could be requiring too big of a margin, while others may be requiring too little. The result is an absence of uniformity in care and potential additional patient costs that could be avoided.

Study raises questions about failure to operate when a second operation seems necessary

One of the more surprising findings of the *JAMA* study was that even when the margin is positive, patients do not always undergo a second surgery. In this study, about 14 percent of patients with cancer cells touching the inked edge did not have surgery a second time.

It is not clear why such operations are not occurring when a second surgery appears to be recommended. The study found that clinical factors such as the type and size of the cancer, the location of the thinnest part of the margin and whether the cancer was diagnosed

[see SURGERY, page 5](#)

SURGERY, from page 4

as malignant could play a role in the decision. Also, the study did not look at factors like individual patient preference, which also could have affected the decision not to operate again.

Advice for patients

What is the take-away message? A second operation is always necessary when the margin is positive and cancer cells are touching the inked edge.

Yet when it comes to the question of how close is too close — how wide the clean margin is — there is no “right” answer at this time.

While wide variation in rates of second surgery may be a problem indicating that better research is needed, it is important not to judge surgeons based on their rates of second surgeries. As Monica Morrow, chief of Breast Surgical Service at New York City’s Memorial Sloan-Kettering Cancer Center, explained in an editorial accompanying the *JAMA* article, a high rate of second surgeries is not always bad: Doctors may have high rates of second surgeries because

they choose to perform a lumpectomy or partial mastectomy in more difficult cases where the tumor is large, instead of insisting on a more aggressive total mastectomy for larger tumors. These doctors could possibly have higher rates of second surgeries but low rates of mastectomies (meaning that they helped patients by avoiding unnecessary mastectomies at the outset).

Also, because there is little evidence on the effects of various negative margin widths on cancer recurrence or long-term survival, it is hard to say precisely what number of second

surgeries is too much or too little.

Additional surgery can be costly and stressful and should be undergone only if medically necessary. If you or a loved one is considering a second breast cancer surgery and still has questions about the right course of treatment after talking to a physician, it may be helpful to seek a second opinion from a different surgeon at another institution. Given the variation observed between doctors and hospitals, the second doctor may have different advice that could assist in making a decision that is right for you. ♦

Does a doctor’s judgment on when to operate get better with experience?

The *JAMA* study on breast conservation surgery rates also showed that doctors’ personal philosophies on when to perform a second operation probably had little to do with their relative amount of experience. When other variables were taken into account, researchers found no association between the average annual volume of initial breast cancer operations performed by a surgeon and the number of times the surgeon chose to perform a second operation. This means that a doctor’s personal judgment on when a second operation is necessary does not change (or improve) over time.

Are your medicines SAFE?



Find out which drugs are safe — and which you should avoid — with Public Citizen’s WorstPills.org and *Worst Pills, Best Pills News*. To subscribe to WorstPills.org, our online database, for only \$15 a year, visit www.WorstPills.org and type in promotional code **PNMAY12** when prompted.

To subscribe to the monthly print edition of *Worst Pills, Best Pills News* for only \$10 a year, please mail a check payable to “Pills News” to 1600 20th St. NW, Washington, DC 20009.

www.WorstPills.org



Nondrug Treatments for Neck Pain Better Than Medications

A study recently published in the *Annals of Internal Medicine* (*Annals*) showed that home exercise and spinal manipulation therapy (SMT) are more effective than pain medications plus muscle relaxants for treating sudden- or recent-onset neck pain. In addition to having greater effectiveness, these nondrug treatments avoid the adverse, systemic side effects that can result from exposure to the various pain medications and muscle relaxants commonly used to treat neck pain.

The results of this study reinforce the importance of one of the 10 rules for safer drug use long promoted in the Health Research Group's other publication, *Worst Pills, Best Pills News*: Make sure drug therapy is really necessary for your medical condition, and ask your doctor to explain all the alternatives, including nondrug treatments. (See the shaded box on this page for the full list of rules.)

Neck pain: overview

Most people will experience neck pain at some point in their lives. It is one of the most commonly reported symptoms in the primary care setting. The causes of neck pain usually are not serious, and in most cases, the pain will resolve with conservative treatment.

Frequent causes of neck pain include muscle strain from poor posture while working on a computer or at a workbench for prolonged periods of time, arthritis involving the spine, whiplash, and sports-related or other types of traumatic injuries.

Neck pain can be classified — based on symptoms and clinical evaluation — into one of the following levels of severity:

- Grade I: No signs of major pathology (such as spinal instability, fracture, infection or tumor) and little interference with daily activities

10 rules for safer drug use

1. Have “brown bag sessions” with your primary doctor. Bring in all of your medications.
2. Make sure drug therapy is really needed. Ask your doctor to explain all the alternatives.
3. If drug therapy is indicated, in most cases (especially in older adults), it is safer to start with a dose that is lower than the usual adult dose.
4. When adding a new drug to your regimen, see if it is possible to discontinue another drug.
5. Stopping a drug treatment is as important as starting it.
6. Find out if you are having any adverse drug reactions.
7. Assume that any new symptom you develop after starting a new drug may be caused by the drug.
8. Before leaving your doctor's office or pharmacy, make sure the instructions for taking your medicine are clear to you or to a family member or friend.
9. Discard all old drugs carefully.
10. Ask your primary doctor to coordinate your care and drug use.

- Grade II: No signs of major pathology but possible interference with daily activities
- Grade III: Neck pain with neurological signs or symptoms, such as numbness, weakness or pain resulting from damage to nerves coming out of the cervical spine
- Grade IV: Neck pain with major pathology

Treatment of neck pain

Options for treating neck pain include drugs, range-of-motion and stretching exercises, SMT and other physical interventions (for example, application of heat or cold, and mobilization techniques).

First-line medications used for treatment of neck pain are acetaminophen (Tylenol) and nonsteroidal anti-inflammatory drugs (NSAIDs; see Table 1 on page 7 for a list of NSAIDs available in the U.S.). For patients whose neck pain does

not respond to these first-line drugs, narcotic (opioid) analgesics may be needed. Muscle relaxants are also frequently used, but limited evidence exists to support their effectiveness.

SMT is an intervention delivered by physical therapists, osteopathic physicians and chiropractors to relieve musculoskeletal pain related to the back and neck. The technique involves manual movement of a joint beyond its usual end range of motion but not past its anatomic range of motion. An audible cracking or popping sound frequently accompanies SMT joint movement.

Annals study overview

Dr. Gert Bronfort and his co-authors conducted a randomized, controlled study comparing three treatments for neck pain administered over a 12-week period. The study, funded by the National Institutes of Health, took place between 2001 and 2007.

[see NECK PAIN, page 7](#)

NECK PAIN, from page 6

Patients participating in the study had grade I or II neck pain for two to 12 weeks. The participants included in the study had graded their pain severity at baseline as three or greater on a 10-point scale, with zero representing no pain and 10 being the most severe pain.

After a careful screening evaluation to exclude serious causes of neck pain and other disabling disorders, patients were randomly assigned to one of three treatment groups: SMT, medications or home exercise.

A group of six experienced chiropractors provided the SMT treatment during 15- to 20-minute visits. The level of the spine targeted by the therapy and the number of treatments during the 12-week period were left to the discretion of the treating chiropractor. In addition to spinal manipulation, SMT subjects also could receive light soft-tissue massage, assisted stretching and hot and cold packs to facilitate the manipulation. When necessary, subjects were also advised to stay active or modify activity.

The home-exercise group received two one-hour training sessions on a regimen of neck and shoulder exercises. This regimen included simple self-mobilization exercises (gentle, controlled movements) of the neck and shoulder joints — including neck retraction (simultaneously moving the head and neck backward while looking straight ahead), neck extension, neck flexion, neck rotation and lateral neck-bending motions, and shoulder blade retraction (moving the shoulder blades toward the spine). Subjects were instructed to do five to 10 repetitions of each exercise up to six to eight times per day.

Finally, the medication group received prescription medications from a licensed medical physician. Visits to the physician lasted 15 to 20 minutes. The first-line therapy administered included NSAIDs, acetaminophen or both. Subjects who did not respond well or could not tolerate these first-

Table 1: Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) Available in the U.S.

buffered aspirin (ASCRIPIN, BUFFERIN)
diclofenac (VOLTAREN)
diflunisal (DOLOBID)
etodolac (LODINE)
fenoprofen (NALFON)
flurbiprofen (ANSAID, OCUFEN)
ibuprofen (ADVIL, MEDIAPREN, MOTRIN, NUPRIN)
indomethacin (INDOCIN)
ketoprofen (ORUDIS)
ketorolac (TORADOL)
meclofenamate (MECLOMEN)
mefenamic acid (PONSTEL)
meloxicam (MOBIC)
nabumetone (RELAFEN)
naproxen (ALEVE, ANAPROX, NAPROSYN)
oxaprozin (DAYPRO)
piroxicam (FELDENE)
salsalate (DISALCID)
sulindac (CLINORIL)
tolmetin (TOLECTIN)

line medications were prescribed opioid analgesics. Muscle relaxants were also used as needed. The treating physicians decided which medications would be prescribed and the frequency of office visits. Advice to stay active or modify activity was given as needed.

Annals study results

Of the 272 patients randomized in the study, 91 were assigned to the SMT group, 91 to the home-exercise group and 90 to the medication group. All subjects in the SMT and home-exercise groups received the assigned intervention. However, six of the 90 subjects assigned to the medication group did not receive any medication because they declined to participate or had concerns about side effects.

The 84 medication-group subjects had the following drug regimens (data is missing for one subject):

- 76 (90 percent) received NSAIDs, opioid analgesics and muscle relaxants

- 3 (4 percent) received NSAIDs and opioid analgesics
- 2 (2 percent) received NSAIDs and muscle relaxants
- 1 (1 percent) received opioid analgesics and muscle relaxants
- 1 (1 percent) received muscle relaxants

The study team assessed the subjects' symptoms, including the primary outcome measure of pain on a 10-point scale, with self-administered questionnaires at baseline before treatment and at two, four, eight, 12, 26 and 52 weeks after being randomized.

On the primary outcome measure of improvement in the level of pain from baseline, the SMT subjects reported significantly more improvement than did medication subjects at eight, 12, 26 and 52 weeks after beginning treatment. The home-exercise subjects had significantly more improvement than the medication subjects had at the 26-week time point, but at other time points, there were not statistically significant differences between these two groups — although there was a consistent trend toward better pain relief in the home-exercise group.

Importantly, there were no statistically significant differences in the improvement in pain between the SMT and home-exercise subjects at any time point, meaning both treatments were similarly successful in treating neck pain.

No serious adverse events were reported in the study. There were a number of expected, nonserious adverse events that are typically seen with the treatments used in the three study groups (see Table 2 on page 8). The study team reported that these adverse events were temporary and required little or no change in physical activity levels.

Forty percent of subjects in the SMT group and 46 percent in the home-exercise group reported adverse events, most of which were related to

see [NECK PAIN, page 8](#)

temporary exacerbation of the neck pain. In contrast, 60 percent of subjects in the medication group reported adverse events that were more systemic in nature, the most common being gastrointestinal side effects, including nausea, and drowsiness. Dry mouth, cognitive disturbances, rash, congestion and disturbed sleep were also reported in the medication group.

Conclusions and study implications

The results of this study demonstrate that both SMT and home exercise are more effective in relieving the pain and physical impairments caused by uncomplicated neck pain than are drug regimens that include NSAIDs, opioid analgesics and/or muscle relaxants. Furthermore, there were no apparent major advantages of SMT over home exercise; the two were similarly successful in treating neck pain.

The study did have two major limitations. First, there was not an untreated control group. Inclusion of such a control group would have allowed researchers to estimate what proportion of patients recover from neck pain without any specific medical intervention. Second, the subjects and the researchers obviously were not blinded to the intervention assigned to each participant, increasing the chances for bias in the study results. Overall, the study was very well-designed.

The types of side effects seen in the medication-group subjects were consistent with the adverse-effect profiles of the three classes of medications used. For example, NSAIDs can cause nausea, abdominal pain, vomiting, gastritis, peptic ulcers and gastrointestinal bleeding. The effects of opioid narcotics can lead to nausea, vomiting, constipation, abdominal pain, drowsiness, cognitive symptoms and dry mouth. Finally, the most commonly used muscle relaxants can cause dry mouth; constipation; difficulty urinating; blurred vision; and

Table 2: Adverse Events During the 12-Week Neck Pain Treatment Period

Adverse Event	SMT Group (91 Subjects)	Home-Exercise Group (91 Subjects)	Medication Group (84 Subjects)
Aggravation of Pain	28 (31%)	37 (41%)	0 (0%)
Headache	5 (5%)	3 (3%)	0 (0%)
Stiffness	5 (5%)	4 (4%)	0 (0%)
Numbness/tingling	2 (2%)	3 (3%)	0 (0%)
Nausea	1 (1%)	1 (1%)	5 (6%)
Disturbed sleep	0 (0%)	0 (0%)	4 (5%)
Congestion	0 (0%)	0 (0%)	6 (7%)
Rash	0 (0%)	0 (0%)	7 (8%)
Cognitive symptoms	0 (0%)	0 (0%)	10 (12%)
Dry mouth	0 (0%)	0 (0%)	10 (12%)
Gastrointestinal symptoms	0 (0%)	0 (0%)	17 (20%)
Drowsiness	0 (0%)	0 (0%)	18 (21%)
Other	4 (4%)	3 (3%)	7 (8%)
Total Number of Subjects Reporting Any Adverse Reactions	36 (40%)	42 (46%)	50 (60%)

Furthermore, there were no apparent major advantages of SMT over home exercise; the two were similarly successful in treating neck pain.

confusion, disorientation and other cognitive side effects.

SMT can rarely cause adverse side effects, including strokes, damage to nerves to the shoulders and arms, and death. In contrast, home-exercise programs have very little risk, except for short-term exacerbation of pain, particularly during the initial phases of the treatment.

Considering the relative benefits, risks and costs of the three strategies for neck pain management evaluated in this study, initial treatment with a home-exercise program appears to be the most advantageous choice for most patients with nonspecific, uncomplicated recent-onset grade I or II neck pain.

For patients who fail to respond to home exercise, SMT administered by an experienced and well-trained chiropractor remains a reasonable second option. Treatment with pain medications generally should be reserved for those patients who fail

to see results from these safer, more effective nondrug interventions.

Finally, for any patients treated with medications, a home-exercise program also should be part of the treatment plan, in order to hasten recovery and minimize the amount and duration of drugs used. ♦

SINGLE-PAYER, from page 3

Think Progress blog that he trusted “government more than insurance companies.” Hawaii and California are two states that have already taken steps in the direction of single-payer or state-based public options.

Similarly, Montana, usually a Republican state but currently with a Democratic governor, has invoked the model of Saskatchewan, its neighbor immediately to the north, citing demographic and economic similarities to the Canadian province. Last year, Gov. Brian Schweitzer asked the federal government for a waiver from all funds for federal health programs (including Medicare, Medicaid and the Veterans Health Administration) in favor of a block grant to build what amounts to a state-run public option.

Under this plan, private insurers would still be allowed to operate, but Schweitzer predicts all residents would eventually opt for the superior government plan. He told Great Falls,

Despite the Obama administration’s best efforts to portray the 2010 ACA as a step toward universal health care, the law actually further entrenches the private insurance industry at the heart of the health care system, while leaving 27 million uninsured and tens of millions more underinsured when fully implemented.

Mont., KRTV News, “It’ll be a lonely place over there at Blue Cross/Blue Shield, I’m afraid.” He is not alone in his prediction. The federal “public option” failed because private insurers feared they would be out-competed by a more efficient government plan.

Repeal and replace?

Meanwhile, what effect a repeal of the individual mandate would have on the prospects of state or federal single-payer plans remains to be seen. Some single-payer advocates submitted an amicus brief to the Supreme Court calling for a repeal of the ACA, apparently with the expectation that the collapse of the law

would pave the way for a nationwide single-payer system. Others have highlighted the positive provisions in the law as a reason to preserve it while continuing efforts on the state level.

What isn’t in question is the obvious equity of a single-payer system. In the March hearings, Justice Kennedy hinted that it may have been more honest for the Obama administration to have enacted a single-payer plan rather than require Americans to purchase a product in the distorted marketplace that is private insurance. More honest? Perhaps. More just? Without a doubt. ♦



Advocates for the people since 1971

Make a contribution to support Public Citizen

For more than 40 years, Public Citizen has been fighting the abusive practices of the “fat cats” — whether it’s Wall Street, Big Oil or Big Pharma. We depend on the generosity of concerned citizens like you to help continue the fight.

Join us today!

www.citizen.org/donate
or Member Services, 1600 20th St. NW, Washington, DC 20009

Product Recalls

March 1, 2012 – April 4, 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 II

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

Daytrana Transdermal System Patch (methylphenidate), 2.2 mg/hour, one patch per pouch, packaged in 30-count boxes. Volume of product in commerce: 18,695 patches. Miscalibrated and/or Defective Delivery System: Out of specification for mechanical peel force and/or the z-statistic. Lot #: 47313, expiration date 07/2012; 47937, expiration date 08/2012; and 47955, expiration date 09/2012. Noven Pharmaceuticals Inc.

Daytrana Transdermal System Patch (methylphenidate), 3.3 mg/hour, one patch per pouch, packaged in 30-count boxes. Volume of product in commerce: 235,440 patches. Miscalibrated and/or Defective Delivery System: Out of specification for mechanical peel force and/or the z-statistic. Lot #: 50890 and 50894, expiration date 12/2012. Noven Pharmaceuticals Inc.

Flutamide Capsules, USP, 125 mg, 180-count bottle. Volume of product in commerce: 7,260 bottles. Adulterated Presence of Foreign Capsule: The firm received a complaint that a flutamide 125-mg

capsule, 180-count bottle had a foreign capsule identified as imatinib mesylate, 100 mg. Lot #: J05761, expiration date 11/2012; J15067, expiration date 01/2013; and J15229, expiration date 04/2013. Teva Pharmaceuticals USA Inc. / Cipla Ltd.

Morphine Sulfate ER Tablets, 200 mg, 100-count bottle. For use in opioid-tolerant patients only. Volume of product in commerce: 2,473 bottles. Presence of Undeclared Color Additive: Product label outsert indicated Yellow Dye #6. Correct nomenclature is Yellow Dye #5. Lot #: 2002900, expiration date 09/2013; 2002901, expiration date 09/2013; and 3035357, expiration date 01/2014. Mylan Pharmaceuticals Inc.

Temodar (temozolomide capsules), 5 mg, five-count bottle. Volume of product in commerce: 15,970 bottles. Impurities/Degradation Products: This recall is due to an out-of-specification result relating to total degradation products detected during stability testing. Lot #: 0HLO008. Schering-Plough Products LLC.

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

4-in-1 Dramatic Play Theater Toys. The recalled children's toys can unexpectedly tip over during play, posing an entrapment hazard to young children. Mega Profit Trading Ltd., at (888) 824-1308 or www.guidecraft.com.

Bicycle Brake Cables for Road Bikes. When the brake cables are installed on Campagnolo-style brake levers, they can detach, causing the brakes to fail and posing a fall hazard. W.L. Gore and Associates Inc., at (888) 914-4673 or www.rideoncables.com.

Bicycles (2010-2012 Model Years). The pedals can crack and break, posing a fall hazard to the rider. Wellgo Pedals Corp., at (855) 840-1400 or www.publicbikes.com.

Ceiling Fans. The two 60-watt light bulbs included with the ceiling fans exceed the fan's maximum wattage, which can cause the ceiling fans to overheat or fail. This poses fire and shock hazards to consumers. Westinghouse Lighting Corp., at (888) 417-6222 or www.westinghouselighting.com.

Easton Raptor Lacrosse Helmets. The chin bar can break, causing the wearer to suffer a jaw or facial injury. Easton Sports, at (877) 279-8545 or www.eastonlacrosse.com.

Feels Real Baby Dolls. The fingers and toes of the dolls can detach, posing a choking hazard to young children. Yan Hong Toys, at (800) 428-4414 or www.lakeshorelearning.com.

Folding Chairs. The chairs can collapse during normal use, posing a fall hazard to consumers. West Elm, a division of Williams-Sonoma Inc., at (855) 262-9744 or www.westelm.com.

Grass and Hedge Trimmers. Fuel can leak from the rubber spacer holding the fuel lines in the fuel tank, posing a fire hazard. Husqvarna Machinery Manufacturing Co. Ltd., at (877) 257-6921 or www.husqvarna.com.

Great American Opportunities Arena Lamp. The electrical design and construction of the lamps poses the risk of an electric shock to

CONSUMER PRODUCTS (continued)

consumers. Great American Opportunities, at (866) 292-9756 or www.arenalamprecall.com.

Lawn Tractors. A drive gear in the lawn tractor's hydrostatic transaxle can fail, causing brake failure and posing a crash hazard to consumers. Hydro-Gear Limited Partnership, at (888) 848-6038 or www.hydro-gear.com.

LED Night-Light. An electrical short circuit in the night-light can cause it to overheat and smolder or melt, posing fire and burn hazards to consumers. American Tack and Hardware Co. Inc., at (800) 420-7511 or www.recall-center.com.

Lenovo ThinkCentre M70z and M90z Desktop Computers. A defect in an internal component in the power supply can overheat and pose a fire hazard. Lenovo, at (855) 248-2194 or www.lenovo.com/aiopsurecall.

Medicine Bottle Storage Containers. The medicine container can open by applying pressure to the latch when it is locked. This could result in unauthorized access to medicine bottles in the container. Locker Brand Inc., at (888) 491-6617 or www.rxlocker.com.

Office Depot Brand Biella Leather Desk Chairs. The weld connecting the seat plate to the gas lift can fail, causing the chair to separate from the base. This poses a fall hazard to consumers. Wonderful Year Inc., at (866) 403-3763 or www.officedepot.com.

Power Foundations or Adjustable Bases for Mattresses. Electrical components in the motor control board can fail and short, causing overheating and posing a fire hazard. Leggett and Platt, at (855) 853-3539 or www.titaniumrecall.com.

Push 'N Snap Cabinet Locks. Young children can disengage the cabinet locks, allowing them access to cabinet contents. This poses the risk of injury due to dangerous or unsafe items. Dorel Juvenile Group Inc., at (866) 762-3212 or www.djgusa.com.

Snowboard Bindings. The binding's baseplate can fracture from impact during use, posing a fall hazard to snowboarders. Bon Hiver Inc., at (877) 456-2320 or customerservice@bonhiver.com.

Topeak Babyseat II Bicycle Carrier Seats. A child can place his or her fingers in the opening at the grab bar's hinge mechanism. When the consumer lifts the grab bar to remove the child from the seat, the child's fingertips can be caught in the hinge mechanism, posing a laceration and fingertip amputation hazard to the child. Todson Inc., at (800) 250-3068 or www.todson.com.

Toy Truck Gift With Boy's T-Shirt. Connections in the toy truck's battery compartment can smolder or catch fire, posing a fire and burn hazard to consumers. Happy Shirts, at (855) 354-2779 or www.happyshirts.com.

Two 3/8" Arch Swing Sets. The welded connection of the sleeve joint to the arch support can crack or break. When this happens, the top swing beam can collapse, causing children on the swings to fall and be injured. BCI Burke Co. LLC, at (800) 356-2070 or www.bciburke.com.

Umbro Boys' Outerwear Jackets. The boys' jacket has a retractable elastic drawstring at the waist, with a toggle that could become snagged or caught in small spaces or doorways, posing an entrapment hazard to children. Hong Kong Genexy Group Co. Ltd., at (866) 217-6800 or www.umbro.com.

Utility and Transport Vehicles. The brake pedal mounting blocks can crack and separate, resulting in a loss of braking ability, resulting in a crash. Club Car LLC, at (800) 227-0739, ext. 3831, or www.clubcar.com.

Utility Vehicles. The fuel tube can scrape against the air-cleaner housing and develop holes, posing a fire hazard. Kawasaki Motors Corp. USA, at (866) 802-9381 or www.kawasaki.com.

Viking Dishwashers. An electrical component in the dishwasher can overheat, posing a fire hazard. Viking Range Corp., at (800) 241-7239 or www.vikingrange.com.

Outrage of the Month! FDA Helps Companies Exploit Patients With Alzheimer's Disease

For the second time in less than two years, the Food and Drug Administration (FDA), at the behest of companies seeking to exploit the large market for Alzheimer's disease, has approved a product with little proven benefit and documented risks.

The first of these two unwarranted FDA approvals of Alzheimer's disease products occurred in July 2010, when the FDA approved a new, high-dose version of Pfizer/Eisai's top-selling but patent-expired Alzheimer's drug Aricept (Aricept 23). The agency approved the drug over the objections of most of its scientists, who noted that the drug did not improve overall functioning but caused considerably more side effects than an older, lower-dose version of the drug.

The most recent example is a dye, Amyvid, which is injected into patients with possible Alzheimer's disease and, on the basis of a subsequent brain scan, is used to detect amyloid plaque in the brains of such patients. A brain scan finding involving amyloid plaque is related to Alzheimer's disease.

After the FDA recently approved this dye, despite strong opposition from several experts in brain imaging and from Public Citizen, the manufacturer, Eli Lilly, hemmed and

hewed in a statement about some of the test's limitations, while cheering its approval.

The ifs, ands and buts in the Lilly press release failed to obscure the fact that this is an inaccurate test, subject to serious physician interpretation differences. The test has been shown to detect amyloid plaque in some patients who do not have Alzheimer's disease and to fail to detect the plaque in some patients who turn out to have the disease. Clearly a financial boon for Lilly, the approval sends another blow to Alzheimer's patients and those who love them.

Approving a diagnostic test that can falsely suggest that someone has Alzheimer's disease can obviously result in considerable anxiety for patients, their families and friends. Considering this decision along with the dangerous FDA decision to approve Aricept 23, the agency's and the drug industry's priorities toward the well-being of Alzheimer's patients seem to be taking a backseat to the well-being of companies such as Lilly and Pfizer/Eisai. ♦

NONPROFIT ORG
 U.S. POSTAGE
PAID
 FREDERICK, MD
 PERMIT #999

Health Letter, Public Citizen Health Research Group
 1600 20th Street, N.W., Washington, D.C. 20009



MOVING? SUBSCRIPTION? ADDRESS CORRECTION?
 Please enter corrections or subscription information below. Return current mailing label. Mail to the address above.

NAME _____

ADDRESS _____

CITY, STATE, ZIP _____

SUBSCRIPTION

One year \$18 Two year \$30 Three year \$42

Enclose your check or money order made out to *Health Letter* CHA444

Printed on recycled paper. 