PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR MARCH 2010 – VOL. 26, No. 3

Patient Safety Advocates Launch Campaign to Reduce Resident Physician Fatigue, Boost Patient Safety

Public Citizen, along with a coalition of public interest and patient safety groups, has launched a campaign to increase public awareness and gather stories about patients who have received inferior medical care from fatigued physicians.

At www.WakeUpDoctor.org, the public can get background information about the correlation between physician sleep deprivation and patient safety, share stories and sign on to a letter expressing support for commonsense regulations to reduce the number of work hours and enhance supervision of resident physicians.

Public Citizen, Mothers Against Medical Errors and other patient advocates also sent a letter (page 3) to the Accreditation Council on Graduate Medical Education (ACGME), the group that oversees the training of physicians in the U.S., calling for shorter shifts and more supervision of resident physicians (also known as medical residents) in an effort to boost patient safety. More than 40 health care, patient safety and other public interest advocates have signed the letter.

In a telephone news conference, residents and experts spoke about the dangers posed by medical residents working shifts as long as 30 hours, frequently with limited support or supervision, leaving them exhausted and prone to mistakes. Residents may work as many as 10 of these 30-hour shifts a month.

"Few, if any, people would fly on a plane whose pilot had been awake and working for 25 to 30 hours. Federal regulations prohibit pilots from flying more than 30 to 35 hours a week," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "But because medical residents work on shifts lasting as long as 30 hours straight, they become fatigued, making them more susceptible to making errors that greatly harm patients. It is likely that there are more deaths in U.S. hospitals each year caused by sleep-deprived doctors than the total annual deaths from plane crashes and train accidents."

> **The scientific evidence linking acute and chronic sleep deprivation with preventable medical errors has mounted steadily over the years.**

The scientific evidence linking acute and chronic sleep deprivation with preventable medical errors has mounted steadily over the years, Wolfe said. "Reducing the length of their shifts is the commonsense approach that both the medical field and consumers need."

Nine years ago, Public Citizen, along with the Committee of Interns and Residents, the American Medical Student Association (both represented at the phone conference) and Dr. Bert Bell, whose work on this issue led to New York state regulations, petitioned OSHA to regulate resident work hours, based on evidence of harm to sleep-deprived medical residents in the form of post-call auto crashes, depression and adverse reproductive effects on female residents. The ACGME unfortunately convinced OSHA that it was doing an adequate job regulating resident work hours and that there was no need for OSHA to step in.

Since then, there is even more scientific evidence of the harm resulting from sleep-deprived doctors but the current ACGME regulations are still too lax, as concluded in a December 2008 study by the Institute of Medicine of the National Academy of Sciences, "Resident Duty Hours: Enhancing Sleep, Supervision and Safety." For example, in contrast to the 30 hour work shift without sleep, currently allowed by the ACGME, the IOM recommended that after no more than 16 hours of work, there had to be protected sleep time for residents.

The ACGME board of directors met Feb. 7-9 to discuss changing its policy on work hours in light of this report. It is still unclear whether the ACGME can improve sufficiently to deter federal regulation of resident work hours, with the increased accountability that would come from such federal regulation.

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PUBLIC CITIZEN

Health Letter

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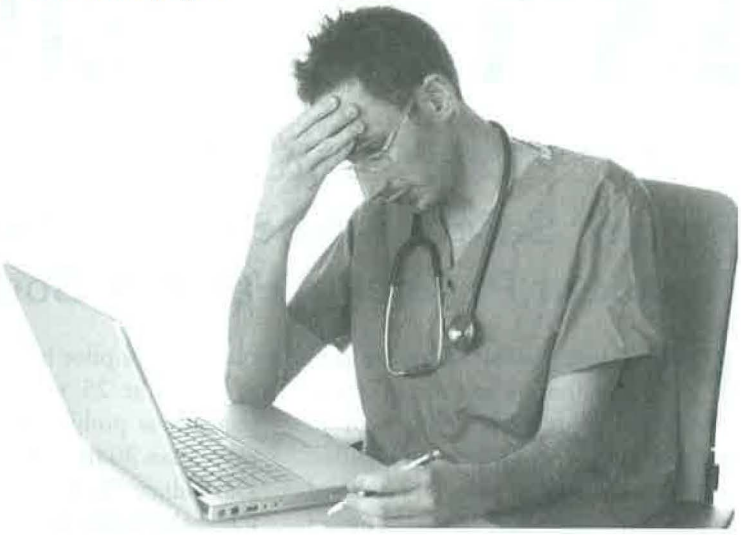

Ample evidence has shown that marathon shifts in excess of 16 hours can have a detrimental effect on a physician's abilities and judgment.

"After 24 hours without sleep, attentional failures at night double and impairment of reaction time is comparable to the impairment induced by drinking alcohol," said Dr. Chuck Czeisler, a professor and director of sleep medicine divisions at Harvard Medical School and Brigham and Women's Hospital. "The clinical performance of physicians — who are used to being at the top of the class — drops to the seventh percentile of their rested performance. Yet, as with alcohol, those affected by sleep loss often do not recognize their impairment."

In 2006, the Harvard Work Hours, Health and Safety Group at Brigham and Women's Hospital in Boston reported that one in five first-year resident physicians admitted making a fatigue-related mistake that injured a patient. One in 20 admitted a fatigue-related mistake that resulted in a patient's death.

"Considerable scientific evidence backs up what common sense tells me: that life and death decisions should not be made by someone who is sleep-deprived," said Dr. John Ingle, fourth-year ear, nose and throat resident at the University of New Mexico and regional vice president of the Committee of Interns and Residents/SEIU Healthcare. "My patients are consistently horrified when they learn that I haven't gone to sleep since they saw me the previous day."

Many suspect that a major factor leading to these exorbitantly long shifts is tradition in the medical field; because seasoned doctors had to endure long hours when they were training, they believe incoming physicians should be subject to the same conditions.

Helen Haskell, the founder and president of Mothers Against Medical Error, became involved in patients' rights after her 15-year-old son died from a preventable medical error. When her son went to the hospital for an elective procedure in 2000, he died from "failure to rescue," or failure to recognize and act upon the signs of serious decline in a patient.

"I know that fatigue must have played a role in my son Lewis's intern's judgment and in her inability to buck the system for the sake of a patient," said Haskell. "There is no way I can ever know how large a role it played, but I do know that in those hours of crisis, the last thing we needed was to have an exhausted, unsupervised young trainee as my dying child's only lifeline."

Another well-known case of a fatal medical error was that of Libby Zion, an 18-year-old whose 1984 death in a New York City hospital spurred new limits for resident work hours. After Zion's death, her father, journalist Sidney Zion,

brought charges against the hospital and the physicians, indicting the medical training system for excessive work hours and poor supervision that, he argued, contributed to poor judgment and medical negligence. As a result of Zion's crusade, New York state has stronger work hours rules than the rest of the country.

For current and future resident doctors, these are cautionary tales.

"Medical training must promote supportive teamwork, not rugged individualism," said Daniel Henderson, health justice fellow at the American Medical Student Association. "Try as we might to ignore our own limits, all doctors are humans, and we all need sleep."

Other industries impose limits on the hours employees work in a given shift to prevent fatigue-related accidents. It's time for the medical field to follow suit.

"Federal regulators and the airline industry long ago recognized that pilots and crews should not have unlimited duty hours. As a result, flight crews' duty time is closely regulated so as to minimize the potential for crew fatigue and its potential lethal consequences," said Art Levin, director of the Center for Medical Consumers and a reviewer of the IOM report. "Patients and medical residents deserve the same protection."

To learn more, to share stories and to sign the letter to the ACGME, visit www.WakeUpDoctor.org. ✦

Letter to the ACGME RE: Optimizing Medical Resident Schedules to Improve Patient Safety

Dear Dr. Nasca:

In December 2008, the Institute of Medicine (IOM) released its landmark report, Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, the most comprehensive study of resident work hours conducted to date. The study reviews the robust evidence base linking fatigue with decreased performance in both research laboratory and clinical settings and makes a number of important recommendations for changes in the current system of training physicians. These include new limits on resident physician work hours and work load, increased supervision, training in structured hand-overs and quality improvement systems, more rigorous oversight and the identification of expanded funding sources necessary to successfully implement the recommended reforms.

In response to the release of this report, we understand that the ACGME formed a Duty Hours Task Force and charged it with recommending revisions to the current duty hour and supervision standards. We are concerned, however, that the ACGME is not adequately weighing the concerns of patients in its deliberations.

Indeed, the available evidence suggests that the public is deeply concerned about the current work hours of medical residents. In a 2002 national public opinion poll conducted by the National Sleep Foundation, 70 percent of respondents reported that they were "somewhat likely" or "very likely" to request another doctor if they learned that their doctor had been working for 24 hours consecutively. Additionally, in a 2004 Kaiser Family Foundation

public opinion poll, 74 percent of respondents listed "stress, overwork, or fatigue of health professionals" as a "very important cause of medical errors" and 66 percent agreed that reducing the work hours of doctors to avoid fatigue would be a "very effective" way to reduce medical errors.

We strongly urge the ACGME to make patient safety a central focus of its response to the IOM's recommendations. There is no scientific evidence to support the idea that a responsibly implemented reduction in working hours as contemplated by the IOM will limit educational opportunities or otherwise leave residents less prepared to practice medicine. Rather, there is abundant evidence showing that the ability of human beings to learn and to perform tasks is compromised by fatigue. Resident physicians are not immune to these universal physiological responses. The IOM recommendations limiting resident hours and workload, training residents in effective techniques for transferring patient information and improving supervision will, we believe, improve patient safety in the nation's teaching hospitals.

Given press reports over the past year highlighting the academic medical community's criticisms of the IOM recommendations as well as information on the ACGME website (Open Letter to the GME Community from Thomas J. Nasca, M.D., MACP, 10/28/09), we are fearful that the ACGME will choose not to adequately act on the evidence at this critical juncture. It is our belief that the ACGME's commitment to quality patient care and resident education should, at a minimum, result in prompt adoption of the IOM recommendations.

Sincerely,
Sidney M. Wolfe, M.D.
Alan Levine
with 40 co-signing groups

Cc: Rep. Henry A. Waxman, Chair, House Energy & Commerce Committee.

The Global Research Neglect of Unassisted Smoking Cessation: Causes and Consequences

The following article was originally published in the Public Library of Science (PLoS) Feb. 9, 2010, available at www.plos.org

By: Simon Chapman, Ross MacKenzie
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As with problem drinking, gambling, and narcotics use population studies show consistently that a large majority of smokers who permanently stop smoking do so without any form of assistance. In 2003, some 20 years after the introduction of cessation pharmacotherapies, smokers trying to stop unaided in the past year were twice as numerous as those using pharmacotherapies and only 8.8 percent of US quit attempters used a behavioral treatment. Moreover, despite the pharmaceutical industry's efforts to promote pharmacologically mediated cessation and numerous clinical trials demonstrating the efficacy of pharmacotherapy, the most common method used by most people who have successfully stopped smoking remains unassisted cessation (cold turkey or reducing before quitting). In 1986, the American Cancer Society reported that: "Over 90 percent of the estimated 37 million people who have stopped smoking in this country since the Surgeon General's first report linking smoking to cancer have done so unaided." Today, unassisted cessation continues to lead the next most successful method (nicotine replacement therapy [NRT]) by a wide margin.

Yet, paradoxically, the tobacco control community treats this information as if it was somehow irresponsible or subversive and ignores the potential policy implications of studying self-quitters. Unassisted cessation is seldom emphasized in advice to smokers. We know of no campaigns that highlight the fact that most ex-smokers quit unaided even though hundreds of millions have done just that. Reviews typically give unassisted cessation cursory attention, framing it as a challenge to be eroded by persuading more smokers to use pharmacotherapies: "Unfortunately, most smokers ... fail to use evidence-based treatments to support their quit attempts"; "If there is a major failing in the UK approach, it is not that it has medicalized smoking, but that it has not done so enough." Clinical guidelines also ignore unassisted cessation. Finally, although the US National Center for Health Statistics routinely included a question on "cold turkey" cessation in its surveys between 1983 and 2000, this question disappeared in 2005.

Because of these prevalent attitudes, smoking cessation is becoming increasingly pathologized, a development that risks distortion of public awareness of how most smokers quit to the obvious benefit of pharmaceutical companies. Furthermore, the cessation research literature is preoccupied with the difficulty of stopping. Notably, however, in the rare literature that has bothered to ask, many ex-smokers recall stopping as less traumatic than anticipated. For example, in a large British study of ex-smokers in the 1980s, before the advent of pharmacotherapy, 53 percent of the ex-smokers said that it was "not at all difficult" to stop, 27 percent said it was "fairly difficult", and the remainder found it very difficult.

We recently hypothesized that research into smoking cessation follows what we call "the inverse impact law of smoking cessation." This law posits that "the volume of research and effort devoted to professionally and pharmacologically mediated cessation is in inverse proportion to that examining how most ex-smokers actually quit. Research on cessation is dominated by ever-finely tuned accounts of how smokers can be encouraged to do anything but go it alone when trying to quit — exactly opposite of how a very large majority of ex-smokers succeeded."

Why does the research concentrate on assisted cessation?

With approximately two-thirds to three-quarters of ex-smokers stopping unaided, our finding that 91.3 percent of recent intervention studies focused on assisted cessation provides support for the inverse impact law of smoking cessation, although further studies are needed to confirm that the bias towards studies on assisted cessation interventions that we discovered is a long-standing one and not peculiar to the years we studied. We believe there are three main synergistic drivers of the research concentration on assisted cessation and its corollary, the neglect of research on the natural history of unassisted smoking cessation. These are: the dominance of interventionism in health science research; the increasing medicalization and commodification of cessation; and the persistent, erroneous appeal of the "hardening" hypothesis.

The Dominance of Interventionism

Most tobacco control research is undertaken by individuals trained in positivist scientific traditions. Hierarchies of evidence give experimental evidence more importance than observational evidence; meta-analyses of randomized controlled trials are given the most weight. Cessation studies that focus on discrete proximal variables such as specific cessation interventions provide "harder" causal evidence than those that focus on distal, complex, and interactive influences that coalesce across a smoker's lifetime to end in cessation. Specific cessation interventions are also

more easily studied than the dynamics and determinants of cessation in populations. Experimental research focused on proximal relationships between specific interventions and cessation poses fewer confounding problems and sits more easily within the professional norms of scientific grant assessment environments, which are populated largely by scientists working within the positivist tradition.

The dominance of the experimental research paradigm is amplified by pharmaceutical industry support for drug trials. More than half the papers we found on assisted cessation were pharmaceutical studies and, unsurprisingly, these were much more likely than papers on nonpharmacological interventions to have industry-supported authors. Companies have an obvious interest in research about the use and efficacy of their products and less interest in supporting research into forms of cessation that compete with pharmacotherapy for the cessation market.

The availability of pharmaceutical industry research funding — often provided without the lengthy processes of open tender or independent peer review — can be highly attractive to researchers. Furthermore, it is often observed that "research follows the money," with scientists being drawn to well-funded research areas. The large pool of research funding for pharmacotherapeutic cessation may cause researchers to gravitate toward such studies while those interested in the natural history of smoking cessation have to secure funding through highly competitive public grant schemes.

This greater availability of funding for certain sorts of research produces a distorted research emphasis on pharmacotherapy that, when combined with the industry's formidable public relations abilities and direct-to-consumer advertising, concentrates both scientific and public discourse on cessation around assisted pharmacotherapy. In 2006, the global NRT market was estimated at $1.7 billion. The pharmaceutical industry places more messages about quitting in front of smokers than any other source: in the USA, there are 10.37 pharmaceutical cessation advertisements per month but only 3.25 government and NGO cessation messages.

The Medicalization and Commodification of Cessation

Tobacco use, like other substance use, has become increasingly pathologised as a treatable condition as knowledge about the neurobiology, genetics, and pharmacology of addiction develops. Meanwhile, the massive decline in smoking that occurred before the advent of cessation treatment is often forgotten. Warner documented this decline, which started following news coverage of the 1964 report of the U.S. Surgeon General. He noted that "per capita consumption likely would have exceeded its actual 1975 value by 20 to 30 per cent" without this decline. Other than the first small pack warnings that appeared from 1966 in the U.S., this effect occurred without any elements of today's comprehensive approaches to tobacco control.

In 1975, Renaud wrote of the fundamental tendency of capitalism to "transform health needs into commodities ... When the state intervenes to cope with some health-related problems, it is bound to act so as to further commodify health needs." The burgeoning commodification of cessation by manufacturers of both effective and ineffective drugs seems to have induced a kind of professional amnesia in tobacco control circles about the millions who quit in the decades before the dominance of the contemporary smoking cessation discourse by pharmacotherapy. As Granfield and Cloud remarked about the substance abuse field's aversion to studying unassisted recovery by narcotics addicts, the dominance of assisted cessation in the tobacco control field "has a common tendency to exclude the experiences of people who do not fit into prevailing models of substance problems and treatment."

The Persistent, Seductive, and Erroneous Appeal of the "Hardening" Hypothesis

This hypothesis predicts that where "smoking prevalence is lowest or the most progress in reducing smoking prevalence has been made, the

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remaining smokers are more likely to be 'hard-core', or refractory to a policy and/or treatment interventions, because the people who have quit were less dependent on nicotine, and/or more motivated to quit." The intuitive attractions of this hypothesis generated an entire US National Cancer Institute monograph. Hardening adherents argue that ex-smokers are dominated by those who were not heavily addicted and so who were better able to quit unaided and that a greater proportion of today's smokers, said to be more addicted, cannot succeed alone and need help. This hypothesis has been heavily criticized. Most recently, data on smoking in 50 U.S. states for 2006–2007 indicate that the mean number of cigarettes smoked daily, the percentage of cigarette smokers who smoke within 30 minutes of waking, and the percentage who smoke daily are all significantly lower in U.S. states with low smoking prevalence, compelling evidence against the hardening hypothesis.

Does research into assisted cessation apply to the real world?

Accumulated evidence from clinical trials shows unequivocally that those who use NRT [nicotine replacement therapy] in trials have 50 percent–70 percent greater success than those using placebo. But clinical trial conditions typically overstate real world effectiveness because of factors such as trial participants getting free drugs and "Hawthorne" effects caused by the research attention paid to participants and the participants' desire to please the researchers with whom they interact. Moreover, Mooney et al. found that only 23 percent of NRT placebo-controlled trials assessed blindness integrity and 71 percent of these trials found that the participants could detect if they had been assigned to the active agent, a rate significantly above chance.

The results from a smaller, but growing, literature examining "real world" use provides a more sobering assessment of the potential of this intervention to significantly improve population rates of cessation. Walsh's review concluded that it is "not yet established that NRT alone is superior to self-quitting in an unsupported OTC [over the counter] environment" and noted major limitations in Hughes' earlier, more optimistic meta-analysis.

While the clinical trial literature consistently shows higher quit rates from assisted than unassisted cessation, population studies show the opposite.

For the clinical trial efficacy of NRT to be replicated in the real world, smokers may need to have some form of support during their cessation efforts but few smokers are interested in engaging with smoking cessation support services. In Australia, for example, in spite of the national quitline number appearing on every cigarette pack and in every government quit message, only 3.6 percent of smokers called the quitline in a year. In 2000–2004, in the UK area with the highest reported cessation support participation rate, only 6 percent of smokers used the available support services. Prospects for engaging larger proportions of smokers in more intensive interventions seem poor.

Overall, population level analyses of the impact of the proliferation, deregulation, and widespread promotion of NRT and other pharmacotherapies have failed to show any significant, sustained impact on smoking prevalence, despite the conclusions of clinical trials. Cummings and Hyland's 2005 review concluded that: "Time series analyses of national cigarette consumption and NRT sales from 1976 to 1998 suggest that sales of NRT were associated with a modest decrease in cigarette consumption immediately following the introduction of the prescription nicotine patch in 1992. However, no statistically significant effect was observed after 1996, when the patch and gum became available OTC. ... annual quit rates as well as age-specific quit ratios remained stable". Similar conclusions were reached for Massachusetts and California. Most recently, Wakefield et al. assessed the impact of televised antismoking advertising, cigarette price, sales of NRT and bupropion (a smoking cessation drug), and NRT advertising by examining monthly Australian smoking prevalence from 1995 to 2006. They found that, unlike antismoking advertising and price, neither NRT or bupropion sales nor NRT advertising had any detectable impact on smoking prevalence. Although this lack of effect may have been due to power limitations (some 40 percent of smokers make an attempt to quit each year, a fraction of these use pharmaceutical aids, and an even smaller fraction quit, which means that extremely large population samples are needed to detect any effect of these interventions), it hardly inspires confidence that assisted cessation makes a major contribution to reducing smoking in populations.

The public is often advised that assistance at least doubles cessation rates. But while the clinical trial literature consistently shows higher quit rates from assisted than unassisted cessation, population studies show the opposite. For example, a 1990 US study found 47.5 percent of those who tried to quit unaided over 10 years were successful, compared with 23.6 percent using cessation programs. Schachter noted that treatment-aided cessation rates may be lower than unassisted quit rates because of selection bias: those seeking treatment are likely to have made unsuccessful quit attempts and may be more failure-prone. In 2008, Shiffman et al. reiterated this point: "Further, smokers self-select for treatment, based on their perceived need and expectations of difficulty quitting ...so treatment-seeking itself

can index risk for failure, undermining the validity of comparisons of outcome between treatment-seekers and non-seekers."

A final example of how promoters of assisted cessation can maintain their position in the face of apparently contradictory results comes from a recent U.S. study of unplanned cessation, which corroborated previous findings by reporting that unplanned cessation attempts were twice as successful as planned attempts and, significantly, that most unplanned quit attempters did not use any assistance. The authors noted that: "Given the evidence that use of medication can double success rates, it is surprising that even without this assistance unplanned quitters were more likely to be successful. It seems important to find ways to combine the favorable prognosis of unplanned quit attempts with the benefit of medication, for example, by ensuring easy, rapid access to medication." They then suggested the removal of barriers to NRT sale such as prescription-only or pharmacy-only status, failing to note that these barriers had already been removed in the USA. The "surprise" expressed by the authors of this paper (all of whom had declared support from the pharmaceutical industry) seems revelatory of the myopic hold that assisted smoking cessation can have on the population-wide picture of how people quit.

The consequences of the research neglect of unassisted cessation

There has been a long history of criticism of the medicalization of everyday life to service social control and medical and pharmaceutical industry profits. As Caron et al. note: "the classic drawback of medicalization is its reductionism, which places excessive emphasis on the biological and individual determinants of disease at the expense of a more holistic perspective that emphasizes the social, cultural, and environmental contributions to disease and illness." The neurobiology of nicotine dependency is well-established, and understanding of its genetics is accelerating. But plainly, with the existence of many millions of unassisted ex-smokers and given the ways that international variations in their distribution reflect social, cultural, and public-health policy variables, smoking cessation in populations is explained by far more than neurobiology and pharmacology.

The persistent messaging that nicotine addiction is refractory and stopping unaided will be futile deflects attention away from what is by far the most common story of cessation: people doing it without professional or therapeutic help. When citizens have common, self-limiting ailments and traits and behaviors are regularly redefined as needing treatment, avoidable iatrogenic consequences and burgeoning health care expenditure can follow. But the steady erosion of human agency as populations lose confidence in their own ability to change unhealthy practices is perhaps of greater concern. Several negative consequences arise from smokers being increasingly imbued with the message that serious efforts at cessation require treatment.

It is understandable that smokers might feel it would be foolish to attempt to stop unaided when unassisted cessation is dismissed in pharmaceutical industry–supported demonstrably misleading propaganda by statements such as: "It is hopelessly outdated to suggest: 'willpower alone is enough to quit'. ... Quitting 'cold turkey' does not generally translate into sustained abstinence from tobacco, and results in unnecessarily low rates of success for most smokers." and: "[the] narrow 'de-medicalized' view of nicotine addiction ...[has] conceivably perpetuated the epidemic [and] contributed to innumerable deaths." Because most assisted cessation attempts end in relapse, such "failure" risks are interpreted by smokers as "I tried and failed using a method that my doctor said had the best success rate. Trying

to quit unaided — which I never hear recommended — would be therefore sheer folly." Such reasoning might well disempower smokers and inhibit quit attempts through anticipatory, self-defeating fatalism.

Why study unassisted cessation?

In any endeavor, whether it be health-related such as weight loss, physical activity or ending narcotics use, or wider achievements such as business success or artistic virtuosity, it would seem reasonable to consider that studying those who had succeeded or excelled might reveal factors that might be valuable to others. Studying the habits, attitudes, routines, and environments of people who succeed where many others fail is commonplace in other fields so why not study unassisted smoking cessation?

The relatively few studies reporting on people who have quit unaided provide important information about factors associated with motivating quit attempts and with successful unaided cessation. Some of these factors are amenable to change via legislation or mass-reach public-awareness campaigns. Smoke-free homes and workplaces, family and social support,

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bold pack warnings, price, and hard-hitting, well-funded campaigns have all been associated with increased cessation activity and success, and relapse has been associated with exposure to social smoking cues.

Warner and Mackay argue that: "We can have our cake and eat it too", stating that further resources and emphasis should be given to treating tobacco dependence as well as to public-health, population-focused approaches to promoting cessation. Certainly, smoking cessation treatment is one of the most cost-effective interventions in modern medicine, and wealthy nations can afford both approaches. However, today's largest tobacco markets are nations with massive populations on low incomes for whom pharmacotherapy is prohibitively expensive. In Indonesia for example, 3 months of NRT costs as much as 7 year's supply of cigarettes, placing NRT totally out of the reach of all but the wealthy. NRT would thus seem to be largely irrelevant to population-wide cessation goals in many low- and middle-income nations.

Such nations emphatically cannot afford "both" and are often still struggling to fund basic primary health care, public-health, and sanitation infrastructures. Population-oriented, mass-reach tobacco control policy and programs are the exceptions in such nations. In our view, it would be a disaster for tobacco control progress if such nations were to be influenced to proliferate labor-intensive UK-style models of assisted cessation before they implemented comprehensive and sustained population-focused cessation policies and programs. In most nations, tobacco control is in its nascent phase. Siphoning resources and scarce personnel into smoking cessation strategies that reach relatively few and help even fewer would be grossly inequitable.

What message should smokers get about cessation?

The persistence of unassisted cessation as the most common way that most smokers have succeeded in quitting is an unequivocally positive message that, far from being suppressed or ignored, should be openly embraced by primary health care workers and public-health authorities as the front-line, primary "how" message in all clinical encounters and public communication about cessation. Put another way, a failure to emphasize that most smokers have always stopped unaided would be like claiming that most domestic cooks attend cooking classes. Along with motivational "why" messages designed to stimulate cessation attempts, smokers should be repeatedly told that cold turkey and reducing-then-quitting are the methods most commonly used by successful ex-smokers, that more smokers find it unexpectedly easy or moderately difficult than find it very difficult to quit, that many successful ex-smokers do not plan their quitting in advance, and that "failures" are a normal part of the natural history of cessation — rehearsals for eventual success. Lessons learned from researching policy tractable, social support, and personal behavioral ("quit tips") variables associated with successful cessation should be fed into policy and program planning. Talk of unassisted cessation being "the enemy" of evidence-based cessation should be roundly criticized as both incorrect and unhelpful. Unfortunately, the ability of manufacturers to promote their products through advertising is likely to "drown out" the perspective we urge. We suggest, therefore, that public sector communicators should be encouraged to redress the overwhelming dominance of assisted cessation in public awareness, so that some balance can be restored in smokers' minds regarding the contribution that assisted and unassisted smoking cessation approaches can make to helping them quit smoking. ✦

What Message Should Smokers Get about Cessation?

>> There is good news about cessation: in a growing number of countries, there are more ex-smokers than smokers.

>> Up to three-quarters of ex-smokers have quit without assistance ("cold turkey" or cut down then quit), and unaided cessation is by far the most common method used by most successful ex-smokers.

>> A serious attempt at stopping need not involve using NRT or other drugs or getting professional support.

>> Early "failure" is a normal part of trying to stop. Many initial efforts are not serious attempts.

>> NRT, other prescribed pharmaceuticals, and professional counselling or support also help many smokers, but are certainly not necessary for quitting.

What You Should Know About Low Back Pain

The following article was originally published in the Annals of Internal Medicine, available online at www.annals.org.

Many people have low back pain at some time in their lives. Back pain is rarely caused by a serious health condition. It often gets better within a few days or weeks. Low back pain can become chronic, meaning that it comes and goes over months to years.

If you have low back pain:

- Do not lift heavy things or do strenuous activity
- Try to keep doing everyday activities and walking, even if it hurts
- Do not stay in bed longer than 1 to 2 days, because it can make your recovery slower

To help you feel better, try some of these things at home:

- Medicines from the drug store to reduce pain, (acetaminophen, ibuprofen—read the labels)
- Heating pads or hot showers
- Massage

See a doctor if:

- Pain runs down the leg below the knee
- The leg, foot, groin, or rectal area feels numb
- Fever, nausea or vomiting, stomachache, weakness, or sweating occurs
- Bowel or bladder control is lost
- Pain was caused by an injury
- Pain is so bad you can't move around
- Pain doesn't seem to be getting better after 2 or 3 weeks

The American College of Physicians and the American Pain Society published guidelines on the diagnosis and treatment of low back pain in December 2007. For a "Summary for Patients" of these guidelines go to www.annals.org/cgi/reprint/147/7/478.pdf.

What You Should Know About Migraine

The following article was originally published in the Annals of Internal Medicine, available online at www.annals.org.

Migraines are headaches related to changes in chemicals and blood vessels in the brain.

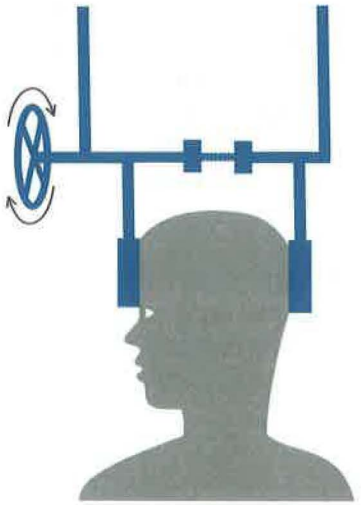
"POUND" (as in "a pounding headache") is one way to remember migraine symptoms:

PULSATILE quality of headache described
ONE-DAY DURATION (duration < 4 hours suggests tension-type headache)
UNILATERAL location
NAUSEA or vomiting
DISABLING intensity

- Good sleep habits, avoidance of foods that trigger migraine symptoms, behavioral therapy (such as biofeedback), and drugs can all help to decrease the frequency and severity of migraine attacks. Migraine sufferers should participate in selecting treatment.
- Over-the-counter drugs, such as acetaminophen, aspirin, and ibuprofen, are usually the first drugs used to treat migraine. When these drugs do not help, prescription drugs may be necessary.
- Talk to your doctor if you think you may have migraine headaches.

Daily drugs to prevent migraine may help you if you:

- Get 2 or more migraines per month
- Are unable to use migraine treatments because of side effects
- Get no benefit from migraine treatment
- Have migraine complicated by nerve symptoms, such visual changes, numbness, or weakness.



Product Recalls

January 26, 2010 - February 12, 2010

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

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

Name of Drug or Supplement; Problem; Recall Information

Pilocarpine Hydrochloride Tablets 5 mg, Rx only, 100 Tablets Sandoz; NDC 0781-5100-01. 9851 bottles of 100 tablets; One lot of Pilocarpine Hydrochloride Tablets, 5 mg may contain out of specification tablets for weight and thickness. Lot #: 100535, exp. date: 03/2011; Corepharma 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 Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC Web site 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

2009 Model Year FX10 Snowmobiles. A bolt in the right front A arm can loosen in the suspension/steering system, resulting in the sudden loss of steering control. This poses a risk of injury or death to riders. Yamaha Motor Corporation U.S.A., (800) 962-7926 or www.yamaha-motor.com.

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21 Pro USA Children's Pullovers and Hoodies. The children's sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. New Mode Sportswear, (888) 899-0888 or www.21prousa.com.

Britax "Blink" Umbrella Strollers. The stroller's hinge mechanism poses a fingertip amputation and laceration hazard to the child when the consumer is unfolding/opening the stroller. Britax Child Safety, Inc., (888) 427-4829 or www.BlinkRecall.com.

Children's Jackets with Drawstrings. The children's jackets have drawstrings through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. GTM Sportswear Inc., (800) 437-9560 or www.gtmsportswear.com.

Children's Metal Necklaces. The recalled necklaces contain high levels of cadmium. Cadmium is toxic if ingested by young children and can cause adverse health effects. FAF Inc., (800) 949-3311 or www.faf.com.

CYBEX Strollers. The stroller's hinge mechanism poses a fingertip amputation and laceration hazard to the child when the consumer is unfolding/opening the stroller. Regal Lager Inc., (800) 593-5522 or www.regallager.com/recalls.

Danbar Knight Hawk Toy Helicopters. The battery housing under the helicopter canopy can overheat while charging, posing a fire hazard. RadioShack Corp., (800) 843-7422 or www.radioshack.com.

CONSUMER PRODUCTS

Discovery Kids™ Animated Marine and Safari Lamps. A defect in the lamp's printed circuit board can cause an electrical short, posing a fire and burn hazard to consumers. Innovage LLC, (888) 232-1535 or www.lamprecall.org.

First Impressions Boy's Three-Piece Santa Set. Loose buttons on the suit's jacket may easily detach, posing a choking hazard to young children. Macy's Merchandising Group, Inc., (888) 257-5949 or www.macys.com.

Glass Water Bottles. The glass water bottle and/or its stopper can shatter when the consumer is removing or inserting the stopper, posing a laceration hazard to consumers. Starbucks Coffee Company, (877) 492-6333 or www.starbucks.com.

Liebherr Built-In 24-Inch Wide Single Door Refrigerators. The refrigerator's door can detach, posing an injury hazard to consumers. Liebherr-Canada Ltd., (877) 337-2653 or www.liebherr-appliances.com.

Nature Wonders HD Pinto Horse Toy Figures. The surface paint coating on the horse contains excessive levels of lead, violating the federal lead paint standard. Blip Toys, (888) 405-7696 or www.bliptoys.com/recall.

Papyrus Brand Greeting Cards with bracelets. The surface paint coating on the bracelets sold with greeting cards contain excessive levels of lead violating the federal lead paint standard. Schurman Fine Papers, (888) 990-9095.

Pull-A-Long Friends Toucan™, Pull-A-Long Friends Alligator™, and Pull-A-Long Friends Sharky™. The toy has wooden components that can break or come loose, posing a choking/aspiration hazard to young children. Manhattan Group LLC, (800) 541-1345 or www.manhattantoy.com.

Rechargeable Batteries sold with MVP 5000 Series Wireless Touch Panels. A defect in the battery can cause the battery pack to overheat and rupture. This poses a fire and burn hazard to consumers. AMX, (800) 222-0193 or www.amx.com.

Special Forces and Police SWAT Toy Gun Sets. The orange tips located at the end of the toy guns' barrels, which are designed to distinguish them from real guns, can easily be removed from the barrels, posing a choking hazard to children. Dollar General, (800) 678-9258 or www.dollargeneral.com.

Talon Hunting Hang-on Tree Stands and Brackets/Straps. The tree stand can unexpectedly detach from the tree when the brackets fail, posing a fall hazard to consumers. Summit Treestands LLC, (800) 241-5559 or www.summitstands.com.

Tiny Tink and Friends Children's Toy Jewelry Sets. A cylindrical metal connector on a charm can contain levels of total lead in excess of 300 ppm, which is prohibited under federal law. Playmates Toys, (888) 810-1133 or www.playmatestoys.com.

Wind Chime Toys. The wind chime toy can be pulled apart exposing sharp metal rods, posing puncture and laceration hazards to the baby. Tiny Love Inc., (888) 791-8166 or www.tinylove.com.

Zippo Slatkin & Co. Candle Lighters. Lighters can produce an excessive flame when adjusted to maximum flame setting, posing a burn hazard to consumers. Zippo Manufacturing Company, (800) 320-7490 or www.Zippominimplrecall.com.

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PUBLICCITIZEN Health Letter

Outrage! "Botox Injections Helpful for Depression?"

This question posed above appeared as the headline in an article on theplasticsurgerychannel.com.

According to the article, "Eva Ritvo, M.D., author and vice-chair of the department of psychiatry and behavioral sciences at the University of Miami, shared a memory in a recent Psychology Today blog. She wrote about seeing the Michael Jackson concert film *This Is It* and feeling moved to tears afterward. When Ritvo tried to cry, she found that she couldn't, due to muscle paralysis caused by a recent Botox injection."

"When I couldn't cry, I quickly stopped feeling sad," said Ritvo. "I felt so odd that I couldn't find those emotions."

Dr. Ritvo suggested that the emotion of sadness seemed to disappear after it couldn't be fully expressed. She said, "the emotions lingered a bit but felt 'unreal' and disconnected," citing "facial feedback theory," which is the connection between the physical expression of an emotion and the intensity of that emotion.

Ritvo asked: "Is that because looking better makes us feel better? Is it because our faces can't provide negative feedback such as frowning, scowling and crying? ... Are we more appealing to others when we look happy and this triggers more positive events in our lives?" Dr. Ritvo discussed the need for new research that could reinforce a link between emotion and the facial effects of Botox.

As we age and encounter more circumstances such as the loss of loved ones, crying and frowning are natural, human responses that express to others, as well as to ourselves, how we feel. Asking whether we are "more appealing to others when we look happy" seems to be denying parts of our humanity.

To purveyors of Botox — the companies and some doctors — depressed people may seem to be yet another market for this neurotoxin. But it seems, even if it works, nothing but ghoulish to try to chemically suppress crying and the emotions connected with it. ✦