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Cover art by Coleen Shin

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# Perspectives on Prescribing

By DEBRA NELSON-HOGAN, DIRECTOR OF EDUCATION AND EDITOR OF *THE PAIN PRACTITIONER*

I was driving home from the Catskill Mountains a couple of weeks ago, thinking about this issue and the complexity of prescribing today. I happened to be listening to an interview with Andrea Tone, PhD, author of *The Age of Anxiety: A History of America's Turbulent Affair with Tranquilizers*. She was describing the birth of tranquilizers in the 1950s and the unprecedented success of Miltown (meprobamate), the first one to hit the market in 1955 and the fastest-selling drug in American history (1). It occurred to me that so many of the practices that we take for granted today were born in and flourished during the early days of Miltown. These include the introduction of “lifestyle” drugs as opposed to medications used for disease management; the accidental discovery of a blockbuster drug while researching unrelated disorders; consumer-driven desire for prescriptions; and the beginning of general practitioners prescribing for diseases that had previously been in the realm of specialists.

In the 1950s, anxiety was viewed less as a medical disorder than a “badge of achievement”—an emblem not only of struggle, but also of success (1). It wasn't that people could not cope, but everyone was working so hard to get ahead. On the surface, this “age of conformity” might appear bland: think of Howdy Doody, Levittown, President Eisenhower, and the golden age of television. However, Tone reminds us that the 1950s were actually pretty frantic. The economic prosperity and growth, plus a bumper crop of babies, created unparalleled stress. This was also the age of polio, atomic anxiety (does anyone out there remember the “duck and cover” campaign in the public schools?), and the ongoing threat that the Russians would invade or infiltrate from within. Women who worked during World War II returned home to be housewives and mothers. This was a lot for Americans to handle, so much so that anxiety and other psychological disorders attained public health crisis status. The psychiatric community wholly embraced talk therapy and psychoanalysis, but this was too costly and time

consuming for the average person. America was ripe for the introduction of an affordable alternative.

Enter Dr. Frank Berger, a German-Czech scientist who, while researching a compound to kill penicillin-destroying bacteria, discovered a relaxant (mephesisin) (1), which enacted muscle relaxation and temporary paralysis in a fully conscious state. In the late 1940s, the drug was sold under the trade name Tolserol for intravenous use in surgical wards to induce preoperative relaxation and help relieve muscle spasms and other debilitating symptoms. But Tolserol had limitations. It was only effective when administered intravenously and was rapidly absorbed. Berger's goal was to “develop a drug as effective as mephesisin but, last longer, and remain potent in pill form” (1). That drug was Miltown, and when it was launched in 1955 by the Carter Wallace Companies, the firm's executives were worried that there wouldn't be any interest in anxiety relief through a pill.

They underestimated consumers. Tranquilizers were “Relatively cheap and easy to take, they bypassed the time and possible discomfort of therapy. They fit snugly into the confines of a doctor-patient relationship: an ordinary person talking to a physician about a routine problem that a seemingly benign ‘emotional aspirin’ or ‘peace pill’...could fix” (1). In fact, people did not see themselves as having a mental illness, they simply were looking for something that would help them function better.

They learned of the little white pill from friends, coworkers, and oddly enough, the entertainment sector. Miltown was quickly embraced by Hollywood as performers used it and talked about it freely. These entertainers included Milton Berle, who “raved about how good Miltown made him feel and how often he took it. Loaded on the goodwill pills, he began to call himself ‘Uncle Miltown.’” At the 1955 Oscar and Emmy awards shows, Bob Cummings, Jimmy Durante, and Jerry Lewis praised the drug (1). It became the standard for chic relaxation, and taking Miltown became a fad. Tiffany and Cartier created special pill boxes and necklaces to carry

the drug, Baskin Robbins advertised a Miltown-flavored ice cream (thankfully, it was only a promotion tool), and it permeated popular culture much as Starbucks does today.

The constant comments by celebrities caught the attention of the FDA, which investigated the link between celebrity endorsement and improper use. Although the claim was unfounded, the FDA did become involved in the debate over whether Miltown was “habit forming” (1). During the 1950s and 1960s, hundreds of consumers wrote to the FDA asking for an opinion on whether the tranquilizer was addictive. The FDA’s response was neutral, but it reminded consumers that any drug that provided pleasurable results had the potential to be habit forming. Tone notes that the FDA’s diplomacy was partly because of the “murkiness of addiction science in this era. Research on prescription sedatives and hypnotics was still in its infancy. The current day distinctions between addiction, habituation, and psychological and physical dependence, pleasure-seeking behavior, therapeutic misuse, tolerance, and withdrawal reactions upon abstinence were still being debated and refined” (1).

We have seen a lot of changes in prescribing over the past 55 years, but the launch of Miltown set the stage for many events. There have been many blockbuster drugs, some of them discovered by accident. Lifestyle drugs have become accepted and expected, and there has been a shift in prescribing from specialists to family practice physicians. No, we don’t hear celebrities touting the benefits of drugs the way that Milton Berle did, but they

do appear on television commercials for direct-to-consumer advertising, though thankfully not for opioids. Instead, celebrity admittance to rehabilitation centers for addiction is increasingly common, reflecting—and perhaps reinforcing—a significant public health problem that health care providers, as well as federal, state, and local agencies, are struggling to deal with.

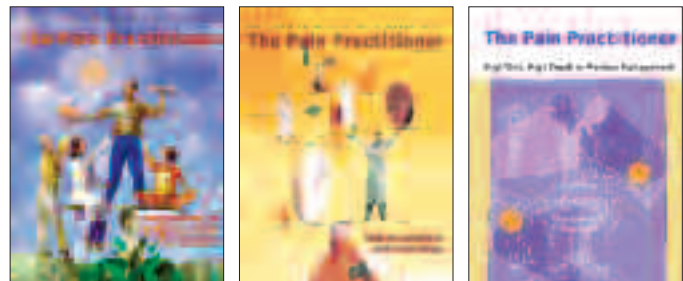
Because of the growing awareness of misuse and addiction, the FDA has attempted to place restrictions on opioids, but a mandatory REMS is still being debated. In the meantime, prescribers are trying to minimize risk while providing optimal patient care, resulting in another age of anxiety. In his article *The Balancing Act*, on page 44 of this issue, Michael Brennan, MD, says, “The early 21st century has put clinicians in the difficult position of trying to address 2 significant public health crises: undertreated pain and the burgeoning problem of prescription drug abuse. As pain clinicians, we straddle these worlds. As much as we want to be the advocates for our patients, we must also be the most outspoken advocates for safe prescription drug use. I never expected to be in such a position, nor do I believe have any of us who have ended up as pain practitioners. But, the reality is that we are not only at the nexus of these problems, we are the nexus.” ■

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## Coming Up Next in

## *The Pain Practitioner*



## Review of the 21st Annual Clinical Meeting



# Taking Action to Ease Pain: Why Public Policy Matters

By REBECCA KIRCH, ASSOCIATE DIRECTOR OF POLICY FOR THE AMERICAN CANCER SOCIETY  
CANCER ACTION NETWORK

Although the dangers of prescription pain medications and their abuse often hit the headlines, we hear far less often about the other side of the story—the individual patients who are suffering and need these medications to ease their pain. But these stories are poignant and unforgettable. Patients’ stories need to be heard, because they are often what move people to action.

Presenting scientifically sound evidence is always important to establish the source of a problem and develop potential public policy solutions to address it. Personalizing those statistics with related stories, however, is the essential ingredient in achieving effective advocacy that gets policymakers to take notice and take action.

It is the power of science, coupled with compelling personal stories, that patient advocacy organizations like the American Cancer Society Cancer Action Network (ACS CAN), the advocacy affiliate of the American Cancer Society, and the American Pain Foundation (APF), use as the foundation for our work to advance pain policies in Washington, DC and in statehouses across the country. Partnerships with professional organizations like the American Academy of Pain Management (the Academy), ACS CAN, and APF are important vehicles for empowering healthcare professionals and their patients to make their statistics—and their stories—heard, so they can be part of the driving force behind needed public policy change.

This past year’s passage of important pain management provisions in the *Patient Protection and Affordable Care Act* (PPACA) and the multiple opioids-focused initiatives undertaken by the Food and Drug Administration (FDA) have made clear that the ultimate conquest of pain is as much a public policy aspiration as it is a scientific and medical challenge. And the mounting evidence of ongoing gaps in obtaining pain relief serves as our rallying cry that calls out the need to do all we can to do better.

Quality of life is important to people. It is important to cancer patients. It is important to survivors. And it is important to their family caregivers. Recognizing this, momentum is building around the concept of promoting more patient-centered care. Public policy presents an auspicious opportunity to promote quality of life as a health system priority AND a health system property. This will require that we all work together to provide a national model for empowering patients to feel and live better, even if they won’t get better.

It is disheartening that while effective medicines are available to relieve cancer-related pain, significant pain assessment and management deficiencies are consistently reported in the clinical settings where patients and survivors get their care. The situation is even worse for patients experiencing chronic noncancer pain, particularly among medically underserved populations.

While cancer receives a great deal of news media attention, the pain that is often associated with cancer and its treatment is rarely mentioned. An article titled “Cancer and the Media” (1) published earlier this year quantified how news reports about cancer frequently discuss aggressive treatment and survival but rarely (fewer than one-third) mention that cancer treatments can result in adverse effects such as neuropathy, pain, or other symptoms that can significantly affect quality of life. The authors make a provocative point that these portrayals of cancer care in the news and the conversations that happen in the clinic may give patients an inappropriately optimistic view of cancer treatments, outcomes, and prognosis. Such articles certainly do little to inform patients and their families about the importance of requesting or expecting pain control as part of their cancer care.

This also contributes to the skewed priorities in our health care system that emphasize cure, often at the expense of comfort. Pain and symptom management represent less than 1% of the entire extramural budget at

the National Institutes of Health (NIH). This translates to a tremendous lack of evidence base to support the remarkable work that members of the Academy and others in active clinical practice are able to do to provide pain relief to patients. Looking forward, public policy change—both state and federal—will be essential to help recalibrate our health system to provide integrated delivery of care that supports quality of life, such as controlling pain, for all patients in all care settings.

This year's enactment within PPACA of 3 major elements of the National Pain Care Policy Act delivered a good start, providing a balanced national public policy framework for promoting pain research, education, and training activities. The provisions were specifically designed to help the public, healthcare professionals, and policymakers better understand the importance of pain management and dispel some of the myths by:

- Authorizing Health & Human Services (HHS) to convene an Institute of Medicine (IOM) conference series on pain that will establish an agenda for action to improve pain research, education, and clinical care in the US. This IOM initiative has already been funded, and is now getting under way. Its findings will be published next year.
- Establishing an Interagency Pain Research Coordinating Committee to develop recommendations for expanding an aggressive program of basic and clinical research across the NIH on the causes and potential treatments of pain. Discussions for populating this committee with professional and patient representation have just begun.
- Creating education and training grants through HHS for healthcare professionals on improving pain care, including specific requirements for addressing barriers to care in underserved populations. Advocacy will be required to have federal funds appropriated to pay for these grants.

With this national policy progress also came some challenges. The dramatic rise in abuse of prescription drugs not only received constant news attention it has also been a focus of many policy initiatives coming out of federal agencies like the FDA.

The FDA chose to carve out its role in drug control last year, launching several major initiatives targeting opioid analgesics and combination pain medicines that could have lasting implications. The FDA has statutory

authority to require a Risk Evaluation Mitigation Strategy (REMS) for any medication known to have serious risks. About 90 such REMS now exist. These REMS can be required as part of the FDA drug approval process or during post-marketing. The current REMS deliberations for certain opioid analgesics represents the latter, and the REMS is geared to ensure the benefits of these drugs continue to outweigh certain risks—namely, addiction, misuse, abuse, and overdose.

But REMS cannot address the nonmedical use problem outside prescribing, leaving a large hole in our efforts to tackle the real sources of drug abuse and diversion. Moreover, Aaron M. Gilson, PhD, of the Pain & Policy Studies Group at the University of Wisconsin has rightly articulated the dueling policy interface that the FDA's opioids REMS presents: "How will we react to a decrease in abuse that also decreases access?" (2)

While no evidence exists to prove REMS will curb abuse and overdose, we already have evidence showing how such activity can harm patient care. Last April, the FDA issued warning letters to 9 companies to stop manufacturing and distributing certain prescription opioids because the products had been developed so long ago they had never received FDA approval. This unapproved opioids initiative had started as largely a housekeeping measure, but it caused significant harm to patients that the FDA clearly had not anticipated.

ACS CAN partnered with the American Academy of Hospice and Palliative Medicine (AAHPM) and the Hospice and Palliative Care Nurses Association (HPNA) in November 2009 to survey these prescribers. The objective was to establish baseline data to share with the FDA to flesh out the fact or fiction of anecdotal stories being heard about opioid shortages and their resulting impact on patient care. The results were stunning, with over 2600 responses from all 50 states confirming that many healthcare professionals were forced to make major adjustments in their prescribing and patient care practices:

- *Well more than half* in both groups (56% HPNA, 72% AAHPM) confirmed they experienced shortage in medication availability.
- *Approximately one-third* (33% HPNA and 44% AAHPM) confirmed that stable patients had to be changed to a new medication because of limited medication access.

Given that learning experience, we know the FDA has also recognized that evaluating the impact of the opioids REMS on prescribing and patient care, and doing so at regular intervals, will be critical to the success or failure of this initiative. We can take some comfort in knowing that the FDA has devoted considerable time and care to this REMS development process, and FDA staff have been consistent in their efforts to hear and use stakeholder input along the way. Much of that input was reflected in the balanced background information that accompanied the FDA's proposed REMS that was considered by its Joint Advisory Committee Meeting in July.

While that initial FDA REMS proposal was voted down by the committees on July 23, 2010 (25 voted no and 10 approved the proposal), we expect that the FDA will now turn its efforts to considering how the expert recommendations can be incorporated to further improve the REMS. Our hope is that the FDA will continue to work closely with stakeholders to determine and agree on clear access measures and the timeline for implementing them to gauge how the REMS is doing and how patients are faring.

Now is the time for health care professional and patient communities to take action together and be part of the effort to help FDA determine and agree on the most useful and appropriate measures and timelines to use for REMS and patient access, as well as the research process we use to implement those measures. Our collaborative engagement will be essential to ensure continued and unfettered access to pain treatments that promote better pain management and improved quality of life. ■

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