



My name is Peter Pitts and I am President of the Center for Medicine in the Public Interest and Director of Global Health Affairs at Manning Selvage & Lee. I have also served as an FDA Associate Commissioner and am presently a Special Government Employee consultant to this committee.

Samuel Johnson said that “the future is purchased by the present.” And that’s as good a place to start as any in a discussion of the impact of direct-to-consumer advertising on the elderly.

According to recent polls, older Americans are more distrustful of the pharma industry and the FDA than the general population—and even more so in the wake of the current debate over drug safety.

Seniors want safe drugs—and rightfully so—but why are they more negative than other groups of Americans? I believe it is because throughout the significant majority of their lives, their only information about the medications they took came from a single source—their doctors. And the only information offered was how to imbibe the pill (with water, with food, minus alcohol, and the occasional caveat against operating heavy machinery). There was no doctor/patient discussion and there was certainly no public conversation.

That was the environment in which today’s senior citizens were born, grew into adulthood, married, raised children and grew grayer.

It was an environment where doctors were gatekeepers and the gate was kept tightly padlocked and second opinions were considered an affront to Marcus Welby, MD.

According to Juvenal, “All wish to possess knowledge, but few, comparatively speaking, are willing to pay the price.” Today we must face up to that dilemma.

Like it or not, America’s senior citizens are 21st century empowered healthcare consumers. Today, the “learned intermediary” has been replaced by the Internet, the patient is the purchaser, and Dr. Welby is a vendor. Managed care directs, “serious and life-threatening” diseases have morphed from polio and diphtheria to cancer, AIDS and Alzheimer’s Disease. There really shouldn’t be any wonder why older Americans—indeed, most Americans—are frightened. The entire healthcare paradigm has changed.

Woody Allen said that “Change is inevitable – except from vending machines. Management guru W. Edwards Deming said that “Change is not required. Survival is not mandatory.”

Change is frightening. In the 21st century, we must all be *pharmaceuti*. And that includes older Americans.

The good news is that an informed healthcare consumer is a healthier citizen. And while information comes from many sources outside of the physician’s office – one of the most pervasive channels is through direct-to-consumer advertising.

Consider the metrics. According to the FDA’s own research, between 3-5% of all doctor visits are scheduled specifically because a patient (otherwise known as a person) saw a DTC ad.

Now we can debate whether or not 3-5% is a lot or a little, but I think we can all agree that it's a significant number.

According to FDA research, of patients who visited their doctors because of an ad they saw, and who asked about that prescription drug by brand name, 87% actually had the condition the drug treats.

And in 6% of those DTC-generated visits, a previously undiagnosed condition was discovered.

According to FDA research, 18% of those recalling ads said DTC ads had caused them to talk to their doctor about a specific medical condition or illness for the first time. This is a remarkable result, suggesting that approximately one-sixth of the adult population who have seen doctors in the past three months have been motivated by advertising to discuss a new topic.

This is particularly germane when it comes to older Americans.

The Centers for Disease Control and Prevention National Health and Nutrition Examination Survey found that nearly one-third of people age 65 or older whom the survey found to have high cholesterol measurements said they had not before been told by a physician or other health professional that they had high cholesterol. Projected nationally, this percentage translates into about 2.1 million people who may have had high cholesterol without knowing it."

Evidence is emerging that large numbers of elderly patients underuse needed medical care. According to a 2004 Health Affairs study that examined the "growing philosophical conflict over the abundance and inequities that characterize the U.S. health care system," there is evidence of significant underuse of prescription drugs. The preponderance of published medical literature and clinical guidelines, according to the article, compels the expansion of pharmaceutical use among Americans.

This view is supported by a landmark RAND Health study published in The New England Journal of Medicine in June 2003, which found that prescription medications were underused in the treatment of seven conditions that clearly involve secondary prevention, including asthma, cerebro-vascular disease, congestive heart failure, diabetes, hypertension, and high cholesterol. These conditions produce many avoidable deaths, along with costly avoidable emergency room visits, hospitalizations, and nursing home admissions. Three of these conditions— diabetes, hypertension, and high cholesterol are now screened for under the new preventive services benefits now covered by Medicare.

Healthcare education and health literacy for older Americans is essential for both saving lives and saving our health care system. And the best way to do both is to get older Americans to talk with their doctors – precisely the proven result of pharmaceutical direct-to-consumer advertising.

Health care information is the consumer's Rosetta Stone – but older Americans shouldn't need a Rosetta Stone to understand the avalanche of health care information that is available to them today.

Dr. Ruth Day of Duke University speaks about the issue of "Cognitive inaccessibility" -- that health care information is disseminated in a way that is not only not understood by consumers but, worse, is misunderstood leading to unintended consequences. She reckons

that only 20% of the information put out by FDA is properly comprehended. Her suggestion (among others) is that FDA initially focus on communicating better with health care providers.

When it comes to DTC advertising there is another type of cognitive issue – cognitive dissonance, specifically when it comes to information presented either via fair balance and adequate provision in television commercials, or the brief summary in print advertising. And you know what they say, the brief summary is like the Holy Roman Empire – it is neither brief nor a summary.

In FDA's 1999 study, **56%** of people who saw a DTC print ad said that they read the brief summary "not at all" or "a little." In the 2002 study that number jumped to **73%** -- a 17% increase. During that same three-year span, those saying they read "Almost all" or "All" fell from 26% to 16%.

In 1999 3% said they weren't aware that there *even was* a brief summary. In 2002, that dropped a full decimal place to 0.3%. In other words, more people know the brief summary is there, and fewer people are reading it. More information often results in less comprehension and, even worse, less interest. When it comes to older Americans this is a crucial issue that must be addressed by academics, the pharmaceutical industry, and the FDA. "In compliance" and "user-friendly" must not be mutually exclusive terms for anyone – least of all older Americans.

A 2007 study in Drug Information Journal discusses the issue of "is less more" and I will make this study available to the committee.

In closing, I urge this committee to ponder the question posed by T.S. Eliot who asked,

"Where is the wisdom we have lost in knowledge? Where is the knowledge we have lost in information?"

Thank you.