#### -Policy æ PRACTICE-

### **Boomers: Speed Alzheimer's Drugs**

Current treatments and policies fail to "adequately address [the] looming public health crisis" of Alzheimer's disease. a survey of U.S. baby boomers has found. Most respondents (80%) said that they are willing to take experimental treatments that have the potential for stopping the disease and preserving their quality of life, "even if significant health risk was involved," the study found. The Web-based survev was commissioned by Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD), a coalition representing patients, caregivers, consumers, older Americans, researchers, and women's health advocates. The survey was conducted by Opinion Research Corp., which sampled 1,009 Americans born between 1946 and 1964. When provided with basic information on Alzheimer's disease, most respondents were extremely concerned about the potential impact on their health, quality of life, and finances as well as on the health care system, ACT-AD said in a statement. Boomers "place top priority on new drugs that could change the course of the disease, feel that FDA should give priority review to those drugs, expect the right to decide whether to use them, and are willing to accept a degree of risk with promising drugs," according to the group. ACT-AD receives support from Elan Corp. and Wyeth Pharmaceuticals, which are developing treatments for Alzheimer's.

#### **Part D Formulary Override Form**

A coalition of physician and pharmacist organizations and insurers, led by the American Medical Association, has developed a form that all physicians can use to request a prior authorizations or coverage of a nonformulary drug under Medicare's Part D benefit. Partners include the American Psychiatric Association, the American Academy of Family Physicians, the American College of Physicians, the National Council on the Aging, the American Pharmacists Association, and America's Health Insurance Plans. "Physicians will now have a simple one-page form to easily communicate to drug plans why a patient needs a specific drug when other similar drugs are also covered by the plan," AMA board member Dr. Edward Langston said in a statement. With the form, physicians can explain why an alternate drug is needed, why a different dose is required, or why the formulary drug is not acceptable. It is available on the Centers for Medicare and Medicaid Services Web site and also at the AMA, AHIP and AAFP Web sites.

#### **Critics Say Generics Thwarted**

At least 14 brand name drugs are due to go off-patent in the next 5 years, representing \$23 billion in potential savings to Medicare Part D, but pharmaceutical manufacturers are doing all that they can to block generic competition, claims the Pharmaceutical

Care Management Association in a new report. PCMA's members—managed drug benefit plans-negotiate discounts with drug makers on behalf of employers and insurers and are under pressure to keep pharmaceutical prices down so they can offer competitively priced plans to Medicare beneficiaries. The organization says that this year alone, \$1.5 billion could be saved on four drugs that are due to lose exclusivity: Zoloft (sertraline), Zocor (simvastatin), Proscar (finasteride), and Pravachol (pravastatin). The Food and Drug Administration just approved a generic pravastatin. The savings assume that 90% of Medicare prescriptions would be switched to generics, and that the generic would cost 60% less than the brand. In 2007, seven popular products—Norvasc (amlodipine besylate), Ambien (zoldipem tartrate), Zyrtec (cetirizine), Lotrel (amlodipine/benazepril), Coreg (carvedilol), Lamisil (terbinafine), and Tequin (gatifloxicin), are due to lose patent protection, noted PCMA, which could lead to \$700 million in savings that year. But the group said that drug companies have opposed legislation that would speed generics to market or that would mandate generic substitution.

#### **Medicare Trustees Report**

The federal Hospital Insurance Trust Fund—better known as Medicare Part A—is not adequately funded to meet the needs of future beneficiaries, according to the annual report of the Social Security and Medicare Trustees. 'The Hospital Insurance Trust Fund is not adequately financed over the next 10 years," the report said. "From the beginning of 2006 to the end of 2015, the assets of the Hospital Insurance Trust Fund are projected to decrease from \$286 billion to \$197 billion, which would be less than the recommended minimum level of 1 year's expenditures." The trustees added that "the financial outlook for the Medicare program continues to raise serious concerns." Senate Majority Leader Dr. Bill Frist (R-Tenn.) took an upbeat approach to the report, pointing out that it showed the costs of the new Medicare prescription drug benefit are significantly lower than in previous reports. "However, the trustees also make it clear that much work remains to be done to address the growth of Medicare spending," he said in a statement. The American Medical Association focused on the report's projected "steep long-term cuts" in Medicare payments to physicians. "[This] report on the dire future of Medicare cries out for reforms to ensure that Medicare will be there for future generations," Dr. Duane Cady, chair of the AMA board of trustees, said in a statement. "Congress must take an immediate step to preserve seniors' access to physicians by tying Medicare physician payments to the cost of caring for

-Nancy Nickell

# **Executive Cites Concerns** About Use of Cancer Drugs

BY JOYCE FRIEDEN

Associate Editor, Practice Trends

WASHINGTON — Payments for drugs to treat cancer deserve more scrutiny. Dr. Lee Newcomer, business leader of Oncology Services for United Healthcare, said at a conference sponsored by Elsevier Oncology.

For example, he continued, United Healthcare decided to take a closer look at 180 breast cancer patients who were prescribed trastuzumab (Herceptin), a drug indicated only for patients who have a HER2/neu gene.

"I asked the oncology office to send us the report; 12% of patients who were getting Herceptin did not have a HER2/neu gene anywhere in their medical records," he said. "That's a dangerous drug. It's got a high incidence of heart failure.

As a result, Dr. Newcomer said he had no choice but to require physicians who prescribed the drug to staple a report showing the patient had the gene to their first Herceptin prescription claim. After the first prescription, "the rest will go straight through," he added.

Another issue is how to make chemotherapy more cost effective. "Right now, in the world of oncology, you have every incentive to use the most expensive chemotherapy regimen that works" because there is more profit in the expensive drugs, said Dr. Newcomer, formerly an oncologist in private practice. "That is part of how you make your practice income. I used to make my income that way."

Dr. Newcomer is considering a program in which United pays physicians the same profit they used to get from each chemotherapy regimen—in the form of a disease-management fee-but the plan also buys the drugs instead of having the physicians buy them.

You let me go out and get the best possible price for that drug, because as United Healthcare, I've got a little more clout than your office does," he said, noting that he spent \$1.1 billion on drugs last

Under that plan, "[oncologists] winyou still keep the margins at your office," he continued.

"I win because patients are going to get a lower premium. [Large pharmaceutical companies] lose, but that's going to happen," he said.

The idea behind the proposal is that "I want to pay you a lung cancer management fee, but have you be indifferent to which drug gives you the best margin, because we're going to go out and purchase it directly from the manufacturers," Dr. Newcomer said. "Your money doesn't come any more from which drug you choose. It comes from the disease-management fee."

Dr. Newcomer also wants to look more closely at off-label use of cancer drugs. This issue came to his attention when he looked at prescriptions for bevacizumab (Avastin), a colorectal cancer drug, and found that over a 4-month period, 80% of the prescriptions were for colorectal cancer, but the other 20% were for "every other cancer you can imagine—head and neck cancer, pancreas, bone, you name it. Every cancer was on that list, and I have to ask, why? Where's the evidence? Who really benefits from that?'

One way to find out the results of offlabel use of cancer drugs is to enroll the patient in a clinical trial of an off-label drug. United already pays patient expenses in clinical trials that are approved by the National Cancer Institute, according to Dr. Newcomer.

The other option, he continued, is to create registries—possibly in conjunction with the Centers for Medicare and Medicaid Services, "and start finding out whether this stuff works [off-label] or not, instead of having every single office in the country try one or two patients and we never gain any knowledge from that endeavor.'

Another area Dr. Newcomer's office is examining is rationalizing end-of-life care for cancer patients.

"This is of personal interest to me because in my six-man [oncology] group, three of us had almost 90% of our patients die in the hospital, and the other three, where I was, had 90% of our patients die in hospice." he said. "As we had discussions about that, it was a difference in philosophy, but we couldn't quite figure out how we would approach what the right num-

Dr. Newcomer referred to a study by the Quality Oncology Practice Initiative, which looked at end-of-life chemotherapy in about 30 oncology practices. The study found that in some practices, patients got no chemotherapy in the last few weeks of life, and in other practices, 40%-50% of terminally ill patients were getting chemotherapy.

'That [last] one sounds a little high. Zero sounds a little low. Where's the norm, and how do we get there?" he said.

This is a big deal, because third-, fourth-, and fifth-line chemotherapy is a huge cost, and we need to figure out what's reasonable. I do not know the answer to that. All I'm asking for is to get the discussion started."

Elsevier Oncology and this news organization are both wholly owned subsidiaries of Elsevier.

## **Patient Safety** News Available

The Food and Drug Administration's Patient Safety News is a video news series that offers information about recently approved drugs, biologics, and medical devices; FDA safety notifications and product recalls; and ways patients can be protected when they use medical products. For more information, visit www.fda.gov/psn.