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Beware Death Panel! Obamacare/HMOs Move To Nix Cancer-Fighting Drugs

by Marcia Merry Baker

Aug. 20—Federal actions have been underway since July, in the case of two Federal Drug Administration (FDA)-approved, life-prolonging, anti-cancer drugs—Provenge (for prostate cancer) and Avastin (for breast cancer)—to potentially disapprove them for Medicare, and for general use, because they extend life at, what is asserted to be, too great a cost. Both drugs are specialized for sub-groups of patients—many of them seniors, with likely terminal cancer, who can live longer if they get the new therapies. If not, they die earlier.

Denying these citizens the right to treatment, is exactly the Hitler principle of "lives not worthy of the expense," which is embodied in the Obama Affordable Health Care for America Act, and its London model, the National Institute of Health and Clinical Excellence (NICE), set up in 1999 under Tony Blair.

Over the last 11 years, the denial of many anti-cancer drugs by NICE, has significantly raised the death rate for whole groups of the population in the U.K. But President Obama on July 7, installed an outspoken advocate for NICE, Donald Berwick, as the new Administrator of the Center for Medicare and Medicaid Services (CMS). He was put in, by a Presidential recess-appointment over the July 4th holiday.

The intent of Obamacare from the beginning, has been to protect money flows to the international financial interests behind the HMO insurance cartel, by cutting treatment and shortening lives. These purposes will be served if pending actions described below, by the CMS and FDA are allowed to proceed. The only remedy is to get Obama out of office.

• **Provenge:** On July 1, the CMS announced an unprecedented step of beginning a year-long evaluation of whether to approve for Medicare payment coverage, an anti-cancer drug already approved by the FDA. By statute, CMS should approve Provenge, because the FDA in April decided it to be "safe and effective." Provenge has been shown in clinical trials to extend lives by over four months for the relevant sub-group of prostate cancer patients.

• **Avastin:** On July 20, one of the FDA's 49 advisory panels, the Oncologic Drugs Advisory Committee, voted 12 to 1, to recommend that the FDA decide to revoke a prior official "indication" that advanced breast cancer victims will benefit from the drug. Avastin was approved by the FDA in 2008, and is in successful use under Medicare and otherwise; it was found to prolong patients' lives by 1 to 11 months. On Sept. 17, the FDA is to announce its decision on whether it will revoke its prior approval.

Lyndon LaRouche said on Aug. 17, "This is exactly the genocide I warned about, dating back to my April 11, 2009 international webcast. This is why Obama gets the moustache. He is the reincarnation of Adolf Hitler. If the FDA decision is ratified, this is the first step towards death camps."

The Avastin, Provenge Therapies

In brief, the particulars of the two drugs in jeopardy are the following.

The drug bevacizumab, patented as Avastin by Genentech (owned by Roche, based in Switzerland), acts to deter angiogenesis, which is the body's formation of blood vessels to serve cancerous masses. The idea is to kill off the cancer tumor's blood-supply system. It is used against cancer in the colon, lung, kidney, and brain. In 2008, on a fast-track decision, the FDA gave Avastin its recommendation for breast cancer treatment as well. Patients receiving Avastin have lived longer, from a month to 11 months, than if not treated with the drug.

The drug sipuleucel-T, often called a vaccine, is patented as Provenge, made by Dendreon Inc., and is

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the first in a new therapeutic class, known as autologous cellular immunotherapies. The vaccine is produced by using the patient's own cells and an immune stimulant. The therapy consists of three infusions in a month, and trials have shown an improved median overall survival of 125 days with the treatment.

For HMOs: Early Death=Cost Effective

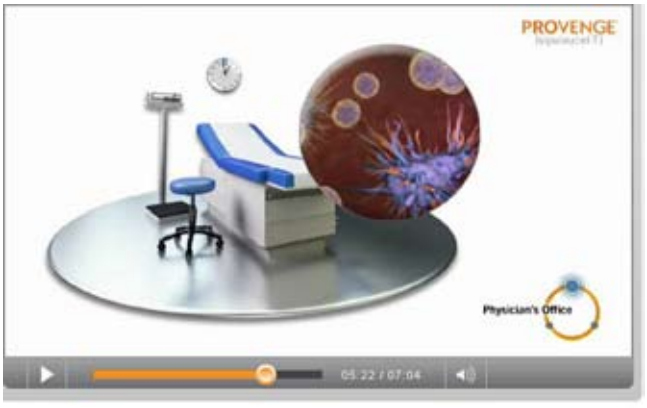
For both Avastin and Provenge, the argument against them is a straight Hitlerian/NICE "cost effectiveness" case. In its July 20 advisory to the FDA to revoke its approval of Avastin, the Oncologic Drugs Advisory Committee asserted, according to medpagetoday.com, "when added to standard chemotherapy, [Avastin] does not extend progression-free survival long enough to be clinically meaningful in HER-2 negative, metastatic breast cancer. . . ."

What they mean by not "long enough," is that patients treated with this drug regimen—according to the studies to date—will live from one to 11 months longer than if they didn't get the treatment. So, 30 to 330 days of life is considered not clinically meaningful.

For the HMOs, this is a dollars-and-cents question. If the FDA goes ahead and revokes its approval for Avastin, and Medicare accordingly withdraws coverage of it, then Obamacare and the HMOs stand to save $8,000 per month per woman with breast cancer. Having her die earlier than if she had been treated, there will be $8,000 to $88,000 more in HMO/CMS "savings" from each woman's death. Of course, physicians can still legally prescribe Avastin for breast cancer, "off-label," which is the term for use of a prescription drug for diseases other than those officially "indicated" by the FDA. That means that just the rich can afford it, and live longer.

If Provenge is not given to a patient who would benefit from it, then Obamacare and the HMOs will save $23,000 per month, or about $93,000 per man who dies off early.

"I shudder at the thought of a government panel assigning a value to a day of a person's life," commented Sen. David Vitter (R-La.), about FDA nixing Avastin, as reported in the London *Daily Telegraph* Aug. 16. "It is sickening to think that care would be withheld from a patient simply because their life is not deemed valuable enough. I fear this is the beginning of a slippery slope leading to more and more rationing under the government takeover of health care that is being forced on the American people."



Two anti-cancer drugs, Avastin for breast cancer, and Provenge for prostate cancer, have been shown by the FDA to extend lives; but the Obamacare death panel wants to rule them out for general use, as not "cost-effective."

Vitter is right on his alarm over rationing and slippery slopes, but he has it dead wrong over who is doing the "taking" over, and who is being "taken" over.

What is required is *more* sovereign government, committed, as President Franklin Roosevelt was, to defending the general welfare from the fascist cartels. Remove Obama from office, and roll back the HMO system.

The U.S. health-care system—from local and state hospital networks, to venerable Federal institutions, such as the FDA (founded 1906), and Medicare and Medicaid (established in 1965)—has been progressively subverted, and is now being taken over, through Obamacare, by the financial interests behind the HMOs—UnitedHealth, Aetna, WellPoint, and others. This was kicked off by the 1973 Health Maintenance Organization Act (signed by President Nixon, cham-

pioned by Sen. Ted Kennedy), and worsened over the decades.

Now, under economic breakdown conditions, the HMO financial interests are demanding new agencies to enforce sweeping powers to kill people, under euphemisms about cost-effectiveness.

Berwick was put in at CMS as their man for the job. He worked in Britain, and describes NICE as having "developed very good and very disciplined . . . models for the evaluation of medical treatment from which we ought to learn." In 2005, he was knighted by Queen Elizabeth for his dedication to practices of cutting health care. In Washington, D.C., in February 2009, he was the keynote speaker at a health-care summit, co-sponsored by Prince Charles' loony, "Prince Foundation for Integrative Health."

NICE Subverts NHS, Kills People

The NICE issue in Britain is not the same as the question of the British National Health Service (NHS) itself, or some fairy-tale notion of socialism. It is Nazi medicine. The NHS was founded in 1948, as a sovereign choice of that nation, similar to government care systems in other post-World War II nations; and whatever its merits or demerits, the NHS functioned for 50 years. However, there is no disputing that in 1999, a new Hitler-style instrument was installed to subvert the NHS: the NICE.

It was set up under Prime Minister Tony Blair (1997-2004), along with his policy advisor Simon Stevens (1999-2001), who then worked for the insurance giant UnitedHealth in the U.K., and today, is a top vice president of UnitedHealth in the United States, specializing in cutting care for seniors.

NICE acted, right from the start, to deny or limit drugs, surgeries, devices, and treatment practices. It fostered privatization of NHS assets and services, to financial outfits such as UnitedHealth. Better named, "Nazi-Inspired Commoner Extermination," the 11-year-old NICE has been under attack year after year, by NHS patients, physicians, and hospitals alike. In just a decade, its policies of selective denial of cancer drugs, kidney dialysis, and other treatments, have increased the death rate for entire age-groups and classes of Britons—which is a Nazi-medicine policy. This was its purpose.

NICE cut care far beyond "rationing," while the physical infrastructure for medical-care delivery was being cut back, in terms of staff ratios, diagnostic equipment, numbers of hospital beds, and so on. NICE has claimed that it is using "clinical effectiveness" among its criteria, but the truth is otherwise. Look at the functioning of the NICE Centre for Health Technology Evaluation, which, in its issuance of formal guidance on what medications will, or will not be allowed, has repeatedly and knowingly caused suffering and death. There are many examples, but consider just those relevant to cancer.

In the case of breast cancer, NICE tried to stop patients from having access to the drug Herceptin. After a big protest movement, limited NHS use was permitted in 2006. This July, NICE disallowed Avaston from payment coverage in the NHS.

In the case of kidney cancer, the drug Sutent has been disallowed for years. Following protests by physicians as well as patients, in January 2009, NICE acquiesced to permitting limited use. Then, in Summer 2009, NICE officially banned the use of Avastin for kidney tumors, saying that Sutent was sufficient.

Physicians, especially oncologists, have fought NICE all along. A March 2009 *European Journal of Cancer* editorial attacked NICE, saying that the agency, in its rulings on which treatments are to be accessible, and under what conditions, has become more restrictive, year by year, and has increasingly based its rulings not on *clinical effectiveness*, but on *cost effectiveness*. In 2008, to take only one example, NICE rejected four drugs for advanced kidney or lung cancer, while acknowledging, as reported in the *Independent* of London, that "the drugs do extend life by up to six months, but the money would be better spent on other patients."

One British voice was especially loud in 2009, warning against Obama following the NICE model, that of London oncologist Dr. Karol Sikora, a professor of cancer medicine at the Imperial College School of Medicine. In a May 12, 2009 *Manchester (N.H.) Union Leader* article, "This Health Care 'Reform' Will Kill You," Dr. Sikora, who is a supporter of the NHS—minus NICE—said, "As a practicing oncologist, I am forced to give patients older, cheaper medicines. The real cost of this penny-pinching is premature death for thousands of patients—and higher overall health costs than if they had been treated properly. . . ." He added, "If NICE concludes that a new drug gives insufficient bang for the buck, it will

caretolive.com

Physicians, medical practitioners, and cancer patients are protesting the Obama Administration's plans to deny coverage for anti-cancer drugs. Shown: a rally calling for approval of Provenge.

not be available through our public National Health Service, which provides care for the majority of Britons....

"Partly as a result of these restrictions on new medicines, British patients die earlier. In Sweden, 60.3 percent of men and 61.7 percent of women survive a cancer diagnosis. In Britain the figure ranges between 40.2 to 48.1 percent for men and 48 to 54.1 percent for women."

This past March, figures were released for the U.K., showing that 20,000 people died needlessly early, over the past year, because NICE turned down outright, four anti-cancer drugs which could have benefited 16,000 people, and provisionally rejected another six drugs that could have saved the lives of 4,000 persons.

Medics Protest Obamacare on Cancer

The largest U.S. organization of cancer physicians and medical practitioners, the American Society of Clinical Oncology (ASCO), with 28,000 members, is protesting the conduct of the Obama Administration, over its calling into question Medicare payment coverage for Provenge. On July 30, the CEO of ASCO, Dr. Allen Lichter sent a letter to the CMS, expressing its concern about the CMS backstepping on Provenge. Excerpts of the letter follow.

"On behalf of our 28,000 members who treat people with cancer, the American Society of Clinical Oncology (ASCO) is writing to express concern about a recent action taken by the Centers for Medicare & Medicaid Services (CMS).

"On June 30, 2010, CMS opened an internally-generated national coverage analysis (NCA) of sipuleucel-T (Provenge).... In particular, we are concerned that CMS may have plans to examine the issue of whether to cover this therapy for its FDA-approved indications. If that is the case, this would be both counter-productive and ill-advised. We believe that CMS is required by the Social Security Act to cover drugs and biologics for FDA-approved indications used in anticancer chemotherapeutic regimens [statutes are cited]....

"The statute thus clearly envisions that Medicare coverage for cancer drugs will flow from approval by FDA, and CMS has historically followed this practice...."

An earlier warning to the CMS came from another group of oncologists. On July 22, the Ovarian Cancer National Alliance stated, "Provenge, a vaccine to treat the recurrence of prostate cancer, has been approved by the Food and Drug Administration (FDA).... Medicare usually covers the cost of FDA-approved anti-cancer therapies. However, the Centers for Medicare and Medicaid Services (CMS) is still reviewing whether it will cover Provenge, and at what rate. The CMS statute states that Medicare must cover therapies that are reasonable and necessary, while the FDA is instructed to approve drugs that are safe and effective. Because of the conflicting Federal coverage and approval requirements, there are some non-FDA approved drugs (called off-label drugs) that are paid for by CMS. However, with respect to Provenge, it appears that CMS is arguing that while the treatment is safe and effective, it may not be reasonable and necessary [i.e., cost effective]. For the first time, an FDA approved anti-cancer therapy may not be covered by Medicare."

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