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AS WE SEE IT

The Lethal Information Gap

The appalling neglect of human life continues unabated, as physicians fail to prescribe drugs that could alleviate or cure disease.

One example of an overlooked drug is cimetidine (Tagamet®). In 1985, The Life Extension Foundation recommended cimetidine as an adjuvant cancer therapy. Back then, cimetidine was a prescription drug. Regrettably, most oncologists refused to prescribe it, even though we provided scientific abstracts substantiating its efficacy.

In a landmark study just released by the British Journal of Cancer, patients with an aggressive form of colon cancer showed a remarkable 84.6% survival rate when treated with cimetidine compared to only a 23.1% survival rate for those not treated with cimetidine.[1] This new study shows that cimetidine improved 10-year survival by almost four-fold!

This is not an isolated report. Since the late 1970s, numerous studies have demonstrated the anti-cancer effects of cimetidine, but because the drug was not “approved” as a cancer therapy, most oncologists did not use it.

Colon cancer will kill 56,000 people in the United States this year. The failure to prescribe this one drug (cimetidine) has resulted in the needless death of thousands of Americans annually.

Now, anyone can obtain cimetidine

Cimetidine is no longer a prescription drug. You can buy it right off the pharmacy shelf under the Tagamet® label or less expensive generics (that say “Cimetidine” on the box).

Cimetidine has shown efficacy against many types of cancer. In the most recent study, however, it was only effective against certain forms of colon cancer. A full report about the use of cimetidine by colon cancer patients can be found in the “Cimetidine and Cancer” article that appears in this month’s issue.

While anyone can now obtain low-cost cimetidine, there are additional anti-cancer drugs that require a prescription, and some are outrageously expensive.



William Faloon

The cancer cost crisis

Optimal cancer treatment can require many expensive drugs. For instance, cancer cells thrive in a low oxygen environment, and many cancer patients are anemic.[2-4] According to a recent study published by the American Cancer Society, anemia increases the overall risk of dying from cancer by an astounding 65%![4]

Life Extension long ago recommended that cancer patients increase their red blood cell count, hemoglobin and hematocrit to the upper range of normal in order to boost the oxygen carrying capacity of their blood.

Speaking of the immune system, the FDA long ago approved a drug called Leukine. This drug partially restores immune cell production lost to the toxic effects of chemotherapy. What few oncologists understand is that Leukine works better when administered concurrently with chemotherapy, rather than waiting to see how much immune damage is inflicted after multiple chemotherapy sessions.[5-7] The primary benefit of Leukine is to stimulate macrophage production to prevent bacterial infection in the chemotherapy patient. Macrophages also engulf cancer cells and assist in their destruction by the immune system.[8]

Since the FDA has only approved Leukine for use after chemotherapy has damaged the immune system, insurance companies aren't paying for this drug to be administered during chemotherapy. Depending on the dose, it can cost over \$1500 a month for Leukine. (Note: Leukine should not be used during radiation.)

Bone loss fuels cancer cell growth

Some types of cancer (breast and prostate) have a proclivity to metastasize to the bone.[9-10] The result may be bone pain which also may be associated with weakening of the bone and an increased risk of fractures.[11-12]

Patients with prostate cancer, for example, are found to have a very high incidence of osteoporosis even before the use of therapies that lower the male hormone testosterone.[13] In settings such as prostate cancer, when excessive bone loss is occurring, there is a release of bone-derived growth factors, such as TGFb-1*, which stimulate the prostate cancer cells to grow further.[14-15] In turn, prostate cancer cells elaborate substances like Interleukin 6 (IL-6), which has as one of its main effects the further breakdown of bone.[16-17] Thus, a vicious cycle results: bone breakdown, stimulation of prostate cancer cell growth and production of IL-6 and other cell products, which leads to further bone breakdown.

The intravenous or oral administration of any of the drugs that are called bisphosphonates, such as Aredia®, Zometa® (intravenous), Fosamax® or Actonel® (oral) can be used to stop this vicious cycle. Such agents stop excessive bone breakdown or resorption and favor bone formation.[18-21] Administration of bisphosphonates should be accompanied by an adequate intake of a bone supplement that supplies all the raw materials to make healthy bone. These include calcium, magnesium, boron, silica, vitamin D and K.

The problem that prostate and breast cancer patients face is that bisphosphonate therapy is approved for treatment only after cancer cells have metastasized to the bone and become clinically apparent by a nuclear medicine bone scan.**

If Aredia were administered monthly to those with certain types of cancers, the risk of bone metastasis could be significantly reduced.[22-23] Life Extension recommended bisphosphonate drugs (like those mentioned above) for certain types of cancer patients more than a decade ago. For many cancer patients, it would be ideal to continue bisphosphonate drug therapy a year or longer. Insurance companies, however, do not pay for bisphosphonates until after the cancer has metastasized to the bone.

Leukine and bisphosphonate-class drugs can save the lives of many cancer patients. The high cost of these drugs, however, often precludes their use. We have previously reported that FDA over-regulation is the culprit behind outlandish drug pricing.[24-25]

Less expensive cancer drugs

Not all cancer drugs are cost prohibitive, but oncologists are ignoring their potential value anyway. In 1996, Life Extension recommended that most cancer patients take a COX-2 inhibiting drug because of solid evidence that cancer cells use the COX-2 enzyme as a biological fuel to sustain their rapid division. Back in 1996, Americans had to import a COX-2 inhibitor named nimesulid from other countries, because this class of drug was not widely available in the U.S.

Now that COX-2 inhibiting drugs like Celebrex® or Vioxx® have been approved, scientists in the United States are hard at work to prove that this class of medication prevents cancer and perhaps even cures it.[30-39]

What has scientists so excited is that experiments in lab animals strongly suggest that drugs like Celebrex could help cure cancer, especially if combined with chemotherapy or radiation.[40-42] One scientist estimates there are 100 separate cancer studies involving COX-2 inhibitors at this time going on worldwide.

FDA Too Slow To Approve New Drugs

A new nationwide poll of cancer specialists sponsored by the Competitive Enterprise Institute (CEI) finds many of them believe the FDA is too slow in approving new medical drugs and devices.

CEI's poll is being released as the agency's drug approval process once again becomes the subject of much debate, with some arguing that drugs are being approved too quickly, while

According to an Associated Press news release on March 30, 2002, doctors are predicting that COX-2 inhibiting drugs may become standard therapy in five to 10 years. There was adequate evidence in 1996, however, to recommend COX-2 inhibiting drugs to cancer patients.

Certain types of cancer cells respond well to statin drug therapy. In advanced primary liver cancer patients, those who received 40 mg of pravastatin survived twice as long compared to those who did not receive this "statin" drug.[43] Statins interestingly are also associated with preservation of bone structure and improvement in bone density. [44-49]

The problem remains that mainstream oncologists are ignoring published findings and are still not prescribing statins, COX-2 inhibitors and other drugs to cancer patients who could benefit. Life Extension members learned about the anti-cancer effects of these drugs many years ago.

Why these lifesaving therapies are ignored?

There are many reasons why the best drugs don't make it into the bodies of those in need. Sometimes the drugs are too expensive and insurance companies won't pay for them.

In other cases, doctors are too busy practicing "assembly line" medicine and are not keeping up with the latest research findings. Many doctors don't want to risk the potential liability involved in prescribing a drug that is not recognized by their peers. These cowardly physicians would rather see their patients suffer agonizing deaths instead of prescribing drugs that are documented in published studies to have potential life-saving effects.

The FDA restricts drug companies from advertising "off-label" benefits of existing drugs. It is cost-prohibitive to obtain FDA approval to make a new disease claim for an existing drug, especially for drugs that do not have long-term patent protection.

The sheer volume of new medical findings is also a problem. It is becoming increasingly difficult for any one doctor to keep up with all the new advances that are announced daily.



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Cancer kills 556,000 American every year, or 5.5 million people per decade. Many of these cancer victims are dying needlessly. The fact that cimetidine can drastically reduce the odds of dying from colon cancer is a stark example of the lethal dangers of not being informed.

The study showing that cimetidine dramatically improved survival in certain types of colon cancer was published in a prestigious cancer journal, but the media has not reported on this breakthrough. There are too many of these kinds of medical discoveries that remain buried in scientific journals. The result is that humans who could benefit from this knowledge also wind up buried instead of cured.

As a member of The Life Extension Foundation, you gain access to information today that is not yet recognized by conventional medicine. Our 22-year track record shows that we have been years (if not

others believe skyrocketing costs and regulatory barriers are affecting drug development. The recent controversy over the FDA's rule for testing pediatric drugs may add another regulatory hurdle to the process.

Highlights of the poll include:

- Almost two-thirds (61%) of the cancer specialists polled believe the FDA is too slow in approving new medical drugs and devices.
- When doctors were asked if FDA regulations helped or prevented them from using promising new drugs or medical devices in the treatment of their patients, there was an almost even split. (43% Help, 44% Prevent)
- Almost eight out of 10 (77%) responded that the FDA's approval process has hurt their ability to treat their patients with the best possible care at least once in their medical careers.
- Almost two-thirds (70%) believe the general public doesn't understand the "human cost" of the FDA approval process—that some people may suffer or die waiting for the agency to act.
- More than half (58%) say the FDA should not restrict information on the use of approved drugs or devices for other unapproved uses, also known as "off-label" uses.

U.S. Senator Bill Frist (R-TN), co-sponsor of legislation in 1997 to reform the FDA, made this statement regarding CEI's poll: "What used to take several years has now been reduced to an average review time of six to 10 months for new drugs. Yet, as many respondents indicated, more needs to be done to further improve the drug review process."

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decades) ahead of mainstream medicine in recommending life-saving therapies.

For longer life,



William Faloon

* Transforming growth factor beta-1.

** Such a scan picks up metastatic cancer that has spread to the bone when there is sufficient bulky disease within the bone to cause enough increased blood flow that the bone scan can detect disease. More sensitive detection methods that pick up circulating tumor cells in the blood (e.g. RT-PCR technology) or findings of microscopic cancer in the bone marrow (immunological staining for micro-metastases or the use of RT-PCR of marrow specimens) have been published but are not approved as yet by insurance companies. (Diel IJ., et al 1992, 1996)

Diel IJ, Kaufmann M, Goerner R, et al. Detection of tumor cells in bone marrow of patients with primary breast cancer: a prognostic factor for distant metastasis. J Clin Oncol 1992 Oct;10(10):1534-9.

Diel IJ, Kaufmann M, Costa SD, et al. Micrometastatic breast cancer cells in bone marrow at primary surgery: prognostic value in comparison with nodal status. J Natl Cancer Inst 1996 Nov 20;88(22):1652-8.

The entire poll can be read online at www.cei.org. The survey—the fifth on this topic sponsored by CEI since 1995—was conducted by the polling company. It included 160 cancer specialists, with a margin of error of +5.1% at the 95% confidence level.

CEI is a non-profit, non-partisan public policy group dedicated to the principles of free enterprise and limited government. For more information about CEI, please visit their website at www.cei.org.

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