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Breast Cancer Breakthroughs

By Scott Gottlieb, M.D.

Thanks to the development of innovative new therapies, breast cancer survival rates in the United States are at an all-time high. Europe has not made such progress because large bureaucracies there have slowed the introduction of new drugs, and because regulations restrict how doctors there can use drugs. Misguided policies from Washington could slow our future progress, and they should be resisted.

Elizabeth Edwards's courageous press conference in late March was a reminder of not only the progress that has been made against breast cancer, but also of how much remains to be done in treating this dreadful disease.

More than 260,000 women will be diagnosed with some form of breast cancer this year. This is always awful news. Yet thanks to earlier detection and clinical research, survival rates have never been higher.

Between 1990 and 2002, deaths from breast cancer declined 2.3 percent annually. Today nearly 98 percent of women with early-stage breast cancer survive at least five years. Many will live long, full lives.

Making these health gains possible are also new drugs, many of them launched over the last few decades. Among them are taxanes, a drug called Herceptin which hones in on a specific receptor expressed by some breast cancers, and advanced hormone therapies such as the aromatase inhibitors. Other innovative therapies, including one that cuts off tumor blood supply called Anti-VEGF and, more recently, a targeted drug called Tykerb, have been approved.

This progress should continue well into the future. More than 500 compounds are currently in clinical trials for all cancers, four times more than

in any other disease area. People with colon cancer also live much longer now, owing partly to a spurt of effective new drugs in recent years; among the newest are Anti-VEGF and Erbitux. In 2004, total U.S. cancer deaths were down by more than 3,000 after years of increases—evidence of a turnaround.

While recent trends in cancer survival cannot be ascribed to the new drugs alone, it is undeniable that more effective, less toxic medicines are having real impact.

A Lone Battle against Cancer?

Yet these improvements are not being realized around the world. Europe should be sharing in the progress against cancer, but large bureaucracies have been erected to contain costs by slowing the introduction of new drugs and restricting how doctors can use them.

Unfortunately, some people want to import the European model here, and in some ways it has already arrived. One current bill on “sole-source,” or very unique drugs, would make Medicare more like Europe, tying access to decisions on pricing.

Since European drug regulators do not allow new medicines to reach patients until government negotiators have extracted a favorable price from sponsors, cancer drugs are often available in the United States months—if not years—earlier. In 2003, when thirty-one new drugs were launched worldwide, about 60 percent were available here

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months before Europe. Between 1995 and 2001, the fifteen cancer drugs approved in Europe and the United States took 468 days to reach patients in Europe, versus 273 days in America. Herceptin was tangled up in a 550-day approval process as the Europeans fought for a lower price, while the United States approved it in fewer than 120 days.

Driving hard bargains means imposing conditions on who can access new drugs by refusing to pay for many uses, even those approved by world regulatory authorities.

There is a price for these policies. A study done in 2003 for Britain's National Health Service found that,

long after its approval, more than a thousand eligible British women with breast cancer were still not receiving Herceptin. Five-year survival for breast cancer caught early in England is 78 percent, compared to 98 percent in the United States. In Germany, a study found that 41 percent of German physicians were treating early breast cancer with taxanes, compared to 60 percent in America at the time. German breast cancer mortality decreased by 9 percent from 1990 to 1998, while mortality in the United States dropped more than twice as much. Overall, between 2004 and 2006, European deaths from breast cancer increased about 1.5 percent, while the number of deaths from colorectal cancer increased 1.8 percent. New research by Columbia University economist Frank Lichtenberg, looking at cancer statistics in Europe, found that use of newer cancer drugs correlates closely with improvements in survival.

Money vs. Lives

Even in the United States, public payers are increasingly resistant to paying for effective new uses of cancer drugs. A large trial of Herceptin, approved for late-stage breast cancer, showed that it reduced recurrence in early-stage patients by a robust 50 percent. But many Medicare

patients in the Northwest could not access the medicine for about five months because Medicare's local insurer would not pay for it. Increasingly, Medicare wants more flexibility to limit or deny payment for new uses of cancer drugs—and some in Congress want to give it to them.

The high cost of developing cancer drugs is translating into high prices. Some of these drugs can run \$50,000 a year, adding to overall health-care costs and creating struggles for some individual patients. But arbitrary restrictions on pricing—and especially on prescribing—set by agencies in Washington will take us off our current track and put us on Europe's pathway.

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People argue about what to do about the rising cost of cancer drugs, but we should first agree on what to resist. Our model for cancer research and cancer-drug development has largely been a success. And continued progress is not likely to come cheap.

The larger problem is our orientation to how we pay for health care. Most people believe insurance is there for when they get sniffles, when it is really there to provide comprehensive care for catastrophic episodes like cancer. So long as insurers are expected to cover the full costs of everyone's routine

expenses, they will increasingly eye the high costs of the extraordinary care experienced by the few. When it comes to expensive drugs to treat cancer, we need to make sure prices reflect the real value drugs provide in how they are being used; prices should not be arbitrarily set under government payment programs.

The fortitude of John and Elizabeth Edwards is inspiring. Society owes it to this family and others like them that therapeutic advances will be made available when we need them most. But medical progress does not come cheaply or easily: it has been hard, expensive, and risky for patients and product developers alike. Europe's lessons show that these advancements could be easily curtailed by poorly planned policies in Washington.