A Cancer Treatment in Your Medicine Cabinet?

WE believe that it might be possible to treat breast cancer — the leading cause of female cancer death — with a drug that can already be found in nearly every medicine cabinet in the world: **Aspirin.**

In 2010, we published an observational study in The Journal of Clinical Oncology showing that women with breast cancer who took aspirin at least once a week for various reasons were 50 percent less likely to die of breast cancer. In 2012, British researchers, by combining results from clinical trials that looked at using aspirin to prevent heart disease, found that aspirin was also associated with a significantly lower risk of breast cancer death.

And yet, until now, there have been no randomized trials (the gold standard of research) of aspirin use among women with breast cancer.

It's not hard to see why: Clinical trials are typically conducted on drugs developed by labs seeking huge profits. No one stands to make money off aspirin, which has been a generic drug since the Treaty of Versailles in 1919, and which costs less than $6 for a year's supply.

Thankfully, the first randomized clinical trial is now going on in Britain, made possible by funding from a nonprofit group, Cancer Research UK. But the British study is looking at four cancers, and won't be done until 2025. If we in the United States had funding to do a similar trial, we could combine our data and get answers much faster. If the United States is to maintain its role as the global leader in biomedical research, it must fund its own trial of aspirin in breast cancer.

Aspirin was originally derived from willow bark, which has been used as a painkiller since the time of Hippocrates. We don't know exactly why it appears to work in fighting cancer. Aspirin reduces inflammation, and that may play a role in inhibiting the growth of tumors — perhaps by slowing the development of new blood vessels that nourish them, or by fighting old cells that keep growing when they should be dying off. It may also inhibit estrogen production, and we know that estrogen fuels the growth of most (but not all) breast cancers.

If we could prove that aspirin was an effective treatment in a clinical trial, it would have major implications, especially for low-income patients. Modern hormonal treatments, used after surgery to try to prevent cancer from recurring, last a standard five years and can cost between $1,200 and $2,300 a year. But not everyone who needs them is actually taking them. Higher co-pays reduce the number of women who fill their prescriptions, according to a 2011 study.

And that is just in the United States. Africa, Asia and Central and South America already account for more than 60 percent of the world's cancer cases and about 70 percent of cancer deaths, according to the World Health Organization. The majority of the impact of the disease will be felt in those areas in the coming decades. Aspirin's minimal cost would make it available in every country on earth, and for millions of women it could mean the difference between some treatment and none.

It may also offer an alternative treatment to women who cannot tolerate widely used cancer drugs because of debilitating side effects. For example, Columbia University researchers found that half of breast cancer patients taking hormonal treatments (specifically, tamoxifen and aromatase inhibitors) were unable to take the drugs for the recommended five years. A survey by the advocacy group Breast Cancer Action found that the predominant reason was joint pain. The most serious possible side effects of taking aspirin are gastrointestinal bleeding and stroke, but they are rare.

If aspirin truly works, we estimate that we could save 10,000 lives per year in the United States, and 75,000 in the developing world.

It won't take much to find out. A randomized study of approximately 3,000 women with Stage 2 and 3 breast cancer, lasting five years, would cost around $10 million. (We wouldn't study women with Stage 1 disease because they have such a high survival rate already, nor women

with Stage 4 cancer, because there is not enough evidence that aspirin would help when the disease has advanced that far.)

Although $10 million is a relatively small amount for a large pharmaceutical company, it is too big for most federal grant mechanisms and nonprofit foundations. Our repeated attempts since 2010 to seek funding through federal grant mechanisms have been rejected.

Yet even as government funding for research is slashed, the government is still willing to test new cancer drugs pushed by pharmaceutical companies, despite very high failure rates for those drugs. Federal grant review panels have no direct financial interest in the studies they approve for funding, but inevitably they are seduced by the more novel treatments — the scientific equivalent of the latest smartphone. And generic drugs, particularly ones as old and familiar as aspirin, just aren't sexy.

There's a saying attributed to Hippocrates that extreme remedies are appropriate for extreme diseases. But in the case of breast cancer, the most simple of drugs may be the next great weapon. **SOURCE: New York Times – May 19, 2014**