

The Approval of Chemotherapy Drugs

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You might think that a study proving increased life expectancy (versus no treatment at all) would be required for a chemotherapy drug to be approved by the FDA. Such proof is not required.

We now have to add another player to our story, and it has to be a government agency. Suppose there is a government agency that decides which car companies can manufacture automobiles. Suppose that the B companies, because of their vast size and money, combined with the natural corruption in government, totally controls this government agency. The high ranking agency employees are routinely "placed" into lucrative jobs by the B companies when they quit the government. And suppose there are many other perks for the government workers by the B companies.

Suppose also that the majority of the members of Congress in this metaphor were either stupid, corrupt or incompetent and they let the government agency do whatever it wanted.

- *"Suppose you were an idiot. And suppose you were a member of Congress. But I repeat myself."
Mark Twain: Manuscript note, c.1882*

With this in mind, I will tell you how drugs get approved. They study how the chemotherapy drug "shrinks tumors" or reduces some benchmark which is supposed to be an indication that the cancer is being defeated. Neither of these things have anything to do with life expectancy. They may or may not indicate whether cancer cells are being killed, but they don't predict life expectancy. They are meaningless numbers. It is like the B companies claiming they are making safer and safer automobiles because the paint on their cars resists sunlight better and better. Fading paint has nothing to do with how long an engine lasts.

This is what the FDA says, on its own web site, about the approval of a chemotherapy drug: Iressa:

*"Accelerated approval is a program the FDA developed to make new drug products available for life threatening diseases when they appeared to provide a **benefit over available therapy** (which could mean there was no existing effective treatment). Under this program, Iressa is approved on the basis of early clinical study evidence (such as tumor shrinkage) suggesting that the drug is reasonably likely to have a valuable effect on survival or symptoms. The approval is granted on the condition that the manufacturer must continue testing to demonstrate that the drug indeed provides therapeutic benefit [i.e. tumor shrinkage] to the patient. If it does not, the FDA can withdraw the product from the market more easily than usual.*

How many clinical trials were performed with Iressa and what did they show? The study on which FDA based its approval included 216 patients 139 of whom had failed treatment with two other chemotherapy treatments. In this trial, approximately 10% of patients responded to Iressa with a decrease in tumor size.

*The sponsor also presented to FDA the results of two large (about 1000 patients each) clinical studies with Iressa as initial therapy for lung cancer. In these studies all patients received, standard combination chemotherapy and were randomly given, in addition, either Iressa or a placebo. In these studies there was **no effect of Iressa on survival [versus the placebo]**, time to further growth of cancer, or on tumor size." (underscore added)
FDA at: <http://www.fda.gov/cder/drug/infopage/iressa/iressaQ&A.htm>*

In other words, in two large studies this drug demonstrated absolutely no increase in survival of cancer patients. It was approved because in other trials 10% of the patients had a decrease in tumor size.

Increased Survival Time

But let's suppose that this particular drug had "increased the survival time" of the patients in a study. Finally, you say, proof that chemotherapy works, I can get back to my chemotherapy. Not so fast. What does it mean to say that a chemotherapy drug "increased the survival time?"

It means that it increased the survival time of patients **relative to some other chemotherapy drug or some other combination of chemotherapy drugs!!** In other words, to my knowledge, never in the history of medicine has a drug company proven that their drug extends the life of a patient **relative to the avoidance of all chemotherapy drugs!** "Survival time" is only measured by comparing one or more chemotherapy drugs to one or more other combinations of chemotherapy drugs.

In other words, this corrupt government agency, allows the B companies approval of their cars as long as they can prove their car model is better than a car model from **another B company!** In other words, the B companies don't have to compare their cars to one of the G company models, only to B company models. If a Company B2 model has a better rear view mirror than a Company B4 model rear view mirror, then it can get approved by the government agency.

Likewise, chemotherapy drugs only have to be compared to other chemotherapy drugs. They do not have to be compared to "no treatment" or "treatment refused" patients, only to other chemotherapy drugs. Nor do they have to be compared to alternative treatments for cancer, such as the Kelley Metabolic therapy.

Study this next quote carefully!

- *"We have a multi-billion dollar industry that is killing people, right and left, just for financial gain. Their idea of research is to see whether two doses of this poison is better than three doses of that poison."
Dr Glen Warner, M.D. oncologist*

In other words, all "scientific evidence" for chemotherapy drugs is to compare them to **each other** or to see if a tumor shrinks or to see if some benchmark changes. Never is chemotherapy compared to alternative treatments nor is it ever compared to no treatment at all. This type of deception is designed to give the public the impression that chemotherapy drugs are constantly improving and soon chemotherapy drugs will actually cure cancer. Nonsense, the chemotherapy drugs are only being compared to each other. What is getting better over the years is their techniques of deception.

"If you can shrink the tumour 50% or more for 28 days you have got the FDA's definition of an active drug. That is called a response rate, so you have

a response..(but) when you look to see if there is any life prolongation from taking this treatment what you find is all kinds of hocus pocus and song and dance about the disease free survival, and this and that. In the end there is no proof that chemotherapy in the vast majority of cases actually extends life, and this is the GREAT LIE about chemotherapy, that somehow there is a correlation between shrinking a tumour and extending the life of the patient."
Ralph Moss

Using the car example, when will the B company cars equal the G company cars in quality? The answer is never because the B company cars are only compared to other B company cars. In the last 80 years there has been virtually zero meaningful progress in chemotherapy drugs. The next 80 years will see about the same improvement as the last 80 years.

Dr. Philip Binzel, an M.D. who used laetrile therapy (one of the commonly used alternative treatments), was asked to take part in a study comparing orthodox medicine to natural medicine. He was excited to participate in the study, here was his chance to prove alternative medicine was far superior to orthodox medicine. I quote from his book:

"During this period of time, the National Cancer Institute (NCI) stated that it wanted to run a study to show the difference between patients treated with orthodox therapy (surgery, radiation, chemotherapy) and those treated with nutritional therapy. I was asked to participate in this study. I went to New York to meet with one of the doctors who was conducting the study. I will call him Dr. Enseeye (not his real name, of course). There was a group of perhaps six or seven of us who had dinner that night with Dr. Enseeye. Betty [Dr. Binzel's wife] and I were seated next to him.

Dr. Enseeye explained the study to me. The NCI would take a group of cancer patients and treat them in the orthodox method. Those of us who were using nutritional therapy would take a similar group of patients and treat them by our method. The NCI would then compare the results. This is the conversation that followed:

"What will the NCI use as a criteria for success or failure in these treatments?" I asked.

"Tumor size," Dr. Enseeye replied.

I said, "Let me make sure I understand what you are saying. Suppose you have a patient with a given tumor. Let's suppose that this patient is treated by one of these two methods. Let's say that the tumor is greatly reduced in size in the next three months, but the patient dies. How will the NCI classify that?"

"The NCI will classify that as a success"

"Why?" I asked.

"Because the tumor got smaller," he replied.

I then asked, "Suppose you have a similar patient with a similar tumor who was treated with a different method. Suppose that after two years this patient is alive and well, but the tumor is no smaller. How will the NCI classify this?"

"They will classify that as a failure."

"Why?" I asked.

"Because the tumor did not get any smaller," he said. Dr. Enseeye went on to say, "In this study the NCI will not be interested in whether the patient lives or dies. They will be interested only in whether the tumor gets bigger or smaller."

*I chose not to participate in this study!"
Philip Binzel - Alive and Well - Chapter 7*

This example also demonstrates by far the most important statistical lie of orthodox medicine. They lie to the public by suppressing the valid "cure rates" of alternative treatments of cancer. Using the above definition of "cure rate" would show the vast superiority of alternative medicine over orthodox medicine.

The best possible way for the B companies to look good, is to totally suppress any statistics that involves the G companies.

In an earlier chapter I mentioned that Vitamin C is a superior treatment to chemotherapy. Orthodox medicine now recommends that Vitamin C should **not** be given to a patient while they are taking chemotherapy. I agree. Should you drop the Vitamin C or the chemotherapy? I would drop the chemotherapy and keep the Vitamin C. Of course read my entire tutorial on alternative treatments before doing anything (there are warnings, among other things).

Summary

Let me summarize this discussion:

The B companies (i.e. orthodox medicine) want to only use the statistic of what percentage of their cars have their original engine after 30,000 miles (i.e. what percentage of patients live for 5 years between diagnoses and death). This avoids letting the public know their cars are pieces of junk.

They suppress any useful statistics that involve cars made by the G companies (i.e. orthodox medicine suppresses valid cure rates for alternative medicine). This avoids letting the public know that the G companies build much superior cars.

The government agency that regulates the automobile industry, like all government agencies, sells their services to the highest bidder, namely the B companies. Thus the B companies are legally protected by Congress (i.e. chemotherapy drugs are legally protected by the FDA and Congress). I have simplified this part of the discussion.

They also get the government to approve their car safety performance because the paint resists sunlight better and better every year (i.e. they use tumor size shrinkage to judge chemotherapy drugs). This gives the public the impression that their cars are getting better and better, and that the government supports their claims that they are superior.

They only compare their car models to other car models made by other B companies (i.e. orthodox medicine refuses to compare the Big 3 side-by-side with alternative medicine, or no treatments at all, using valid measurements of life expectancy and quality of life). This gives the public the impression that the B

companies will soon be making cars just as good as the G companies. But of course they never mention the G companies.