

Re: Strange Illness For Over One Year, Please Help!

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- *From:* Susan <nevermind@xxxxxxxxxx>
 - *Date:* Fri, 07 Oct 2005 20:09:23 -0400
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x-no-archive: yes

Robert wrote:

"Susan" <nevermind@xxxxxxxxxx> wrote in message
news:3qo8ijFqld3aU1@xxxxxxxxxxxxxxxxxxxx

x-no-archive: yes

Robert wrote:

It's not a high volume test. We send ours out to three states over, thousands of miles away. There is no money there. The people who perform and report the tests do so for their pay check.

We do

what are employers tells us to do. There are procedures approved by the

FDA

recommendations by the CDC and others like the American Society of Microbiology. Everything is transparent. There are hospital laboratory inspections pertaining to the reporting of Lyme disease. You don't agree with that then start your own laboratory and pay your employees to

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report

out a single band for Western blot testing as reactive and get nailed

and

your license pulled. You can also have legal action concerning

inducements

for doctors by providing testing which caters to their interest in maintaining their business instead of following accepted referenced procedures. In short you are altering your reporting to generate

business.

The daily volume we deal with is averaging about 2500 tests per day and only get maybe one test request for lyme's or lyme in reality Bb

serology in

about a week at most. That should make you very happy because serology

is

useless according to you.

I'm referring to the financial incentives of the investigators who develop the tests, not the folks who buy the kits and perform them.

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Susan

The original investigators are often NIH research grants that are given to university based research teams. A good example is the new test by the UCSD group involving a new test for oxidized lipids. University based research and government funded research is handed to private companies for specific development. They are handed the patents by the government for production. The government is not in the business of manufacturing pharmaceuticals or diagnostic tests based on antibodies which are patented.

Once the kit is developed and made for clinical use then the FDA must grant the approval based on clinical studies. The UCSD people can do the test but is marked for research purposes only and no claims can be made upon how it is interpreted. The interpretation has not be evaluated. That is the whole point of the clinical study.

Private companies are in the business to make money. All the recent developments in technology have been because of money.

Take a poor country and see how much technological development there is. The production of monoclonal antibodies from polyclonal antibodies have revolutionized the industry of immunology. This is a much more sensitive and much more specific break through. Some people that were typed as RH negative actually type as RH positive with new monoclonal anti-D. Monoclonal antibodies are being used in cancer treatment.

Private companies making money is such a lame excuse. Are there rip-offs? Yes, so you regulate, fine and put in prison those that are fraudulent or what ever.

Next argument is that the FDA is corrupt and then the government is run by big business and how much you love president Bush.

If you have specific concerns about a company that is saying they have a sensitivity of 99% in detecting lyme's disease then report them to the FDA. The ads are written for professionals who know what a comparison or correlation study is. It might say it correlates with the western blot or correlates with a certain definitive stage of disease or any number of things. I don't even look at those ads.

The FDA has the option of pulling all those tests off the market if they want to. A not well known fact is that Abbott laboratories were manufacturing many test reagent systems that were pulled by the FDA for not submitting complete correlation studies or incomplete studies. One test was an automated 20 minute test for hepatitis B that was in use. It was pulled and the FDA fined them and now we use a 2 and a half hour manual procedure. I was pissed. The manufacturer didn't want to pursue or do the studies because the platform or instrument was becoming obsolete. It has a new instrument that it will be available next year.

There was a pregnancy hormone test manufactured by them also that involved a tragic case in which a women was tested and found positive for HCG a pregnancy hormone. She was not pregnant and so it was assumed to be a malignancy. They took out her uterus and she still tested positive for that hormone.

It was a false positive and she never had a malignancy.

The FDA got involved and make the manufacturer to label the results as " not to be used as a tumor marker". That was just one case and they got involved.

If I make a mistake in carrying out the procedures incorrectly and report out a wrong result or an error in performance and contact the manufacturer

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by phone on trouble shooting as to what happened or why, the manufacturer will write down my name and the nature of the error and the FDA will be contacted by them. It may mean a rewriting of the package insert to instrumentation alterations by the manufacturer to reduce errors or nothing at all.

The FDA has and can act in what you are saying.

I have direct experience with that first hand. The clinical laboratory is not a free for all where anyone can do anything they please. We don't experiment with anything.

Robert, are you blissfully unaware that almost everyone in the medical investigation business is convinced that trial outcomes are being influenced by investigator's financial stakes in the products they're studying? This includes NIH staff who have decided they'd rather quit than behave ethically in this regard.

You don't get out much, do you?

Susan

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