Dear Residents,
I just finished watching an expose' on the clinical drug trial process for pharmaceutical companies. If you watched this on NBC Dateline about this, I know you were scared to death. Essentially for a drug to be approved, all must be approved for testing in humans after animal trials. They must have an IRB (institutional review board) approve the trial. This is true for any research project. Most universities have their own IRBs, and are very respectable. However, there are private for-profit IRBs that might not be doing their homework as well, even though most are very good. I have had experience with university IRBs and the reviewers are top notch. Where we see some problem, as pointed out by Dateline, are these contract IRBs, which are sometimes hired by the pharmaceutical companies to request approval for human testing. Unfortunately, with the globalization of our world alot of these are carried on in other countries, and it may be that their standards are not up to the USA. Before an experimental drug gets to human trial, there has been many levels of evaluation. Reputable drug companies are reall ynot the problem, but we still need to be aware of the process and question each drug approved.
Where do they get their volunteers to be human subjects? Some private and university physicians ask their patients to consider experimental drugs on a trial if the standard therapy is not working. There is nothing wrong with this. But other country's pharmaceuticals recruit less than optimal candidates because they want the money. You had to see the TV program.
Dateline created a fake research company to request human testing on a drug that had already been pulled from the market, because it caused hypertension and strokes. The drug was Vioxx. It is an anti-inflammatoy drug similiar to Celebrex. They applied for approval from a private IRB with all the credentials but the drug was already pulled. The experimental fake drug was approved. What they showed was these review boards are not always scrutinizing the

requests for human testing to the highest degree. This puts the human volunteers at undue risk.
I realize that this is a TV program, and it is exposing a problem with the process of clinical trials. These trials are necessary for any drug to be aproved. Unethical behavior is not tolerated by the FDA and is responsible for all drug testing. However, there is great criticism of that federal agency at the present time.
The reason I bring this to your attention is that cancer and other patients are recommended for clinical trials all the time, and as long it is through a reputable university system, I would certainly welcome the trial. Dr. David Kessler, former FDA Commissioner, said on Dateline, that there needs to be a more aggressive system for monitoring these trials.
Dateline admits that 99% of the drugs we are taking are safe, but it is a warning to us all that we must question every drug we take and look up on the internet or ask our doctor what the side effects are, and will they interfere with the other drugs we are taking. Doctors have quick reference books on all of this. Also, ask your pharmacist. BE INFORMED! That is what my Medical Report is all about.
Happy Trails! Dr. Sam
Sam LaMonte, M.D., FACS