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Moving Medication to Market More Quickly

SPEEDIER DRUG APPROVAL PROCESS ULTIMATELY HELPS OR HINDER OUR HEALTHCARE SYSTEM

Many are eagerly awaiting approval of certain drugs whether it be to cure a patient or to realize the research put into the development of the drug. Would a speedier drug approval process ultimately helps or hinder our healthcare system? You are listening to ReachMD, The Channel for Medical Professionals. Welcome to a special report on public policy. I am Dr. Larry Kaskel, your host, and joining me today is Peter Pitts, cofounder of the Center for Medicine in the Public Interest, and Senior Vice President for health affairs at Manning Selvage & Lee.

DR. LARRY KASKEL:

Mr. Pitts, welcome to the show.

MR. PETER PITTS:

My pleasure, thanks very much.

DR. LARRY KASKEL:

Well, can you kind of dive in a little bit into the process of actually bringing a drug to market, how lengthy and how expensive it is?

MR. PETER PITTS:

Well, I was associate commissioner of the FDA and one of the things that the FDA really prides itself on is bringing drugs to market as quickly and as safely as possible, so I think the first thing to understand is that bringing drugs to market more swiftly means nothing if they can't also be brought to market more safely and that's exactly where I think industry and academia and the FDA are moving both in the US and other regulatory bodies globally. The way a drug comes to market now really is in 3 phases, the third phase being FDA regulatory review. A drug has to be invented. Obviously, it has to be brought to a point where it can be tested for safety and efficacy and then in large scale, human trials and clinical trials and once it reaches the FDA, the FDA will review all of the information, ask questions, ask for more information, ask for the company to define certain questions that the agency has and then only after that will the agency decide whether or not the drug is safe enough and effective enough, whether the risk benefit balance is appropriate enough for that drug to be brought to market and now because of new legislation, there is now something that could basically be called phase 4 where the FDA can ask a company once a drug has been approved and is on the market to do post market approval studies to see how the drug is doing and what new things we have learned about the risks and the benefits of that particular drug.

DR. LARRY KASKEL:

Isn't that something the FDA was supposed to be doing?

MR. PETER PITTS:

Yes, the FDA has been doing it, but it has been given the regulatory authority to demand that it be done, so it's given the FDA a little bit more muscle to make sure that what it wants to be done actually gets done.

DR. LARRY KASKEL:

What is the current relationship between big pharma and the FDA? How close is it, how incestuous is it, you know, what's happened in the last 8-10 years.

MR. PETER PITTS:

You know people who say that the FDA is "in industries pocket" really have no idea what's going on. Industry lives in abject fear of the FDA. The FDA is an agency of about 10,000 people. The division within the FDA, which is called CDER, the Center for Drug Evaluation and Research, which reviews the drug applications and post market applications and deals with all the safety issues is staffed 100% by career medical officials. There is not one political appointee in the Center for New Drugs or the Center for Biologics. So when people think that the FDA kowtowing to the industry, they really are completely ignorant of the situation, it's really the complete reverse.

DR. LARRY KASKEL:

But doesn't big pharma pay like royalty fee or actually pay part of the FDA salary.

MR. PETER PITTS:

Well, the industry pays user fees, which means that they pay the FDA to review their application, not to approve them, but to review them, and I think if you look at the FDA actions over the last 5 years, anybody who would say that the industry is kowtowing industry, either doesn't read English or does not understand the implications of what's going on.

DR. LARRY KASKEL:

So, let's say a medication actually makes it out of clinical trials successfully, then what happens to get that medication covered by, let's say, initially by Medicare, what has to happen?

MR. PETER PITTS:

Well, that's not an FDA process. Once a drug goes through clinical trials and is approved by the FDA and gets basically a license to be sold in the United States, then the center for Medicare and Medicaid services, which is called CMS, which is the government body that runs Medicare as well as various private insurance companies throughout the country, make the decision as to whether or not they feel that drug should be reimbursed and those decisions are based on a whole bunch of things. One is that is it the only drug that treats various disease in which case it's generally always reimbursed, you know, is it more effective than other drugs on the market, but as science evolves and we begin to understand that if you have let's say 5 therapies in a category say statins for high cholesterol that one statin is not the same as another statin and that different people respond differently to different types of medications for the same disease and that really is where pharmacogenomics or the science of the genome comes into play, but now that we can test people to find out whether there are quick or slow metabolizers and what type of medicine they may or may not respond to best, we can more precisely prescribe what is the proper medicine as well as the proper dose and the way that this will manifest itself initially is we will learn what drugs should not be prescribed to which people. So we will be able to prescribe more safely, but ultimately the way that insurers make their decision is individually per drug on how effective it is, the general size of the population and what other drugs are available within the therapeutic category.

DR. LARRY KASKEL:

Where are we in the evolution of pharmacogenomics?

MR. PETER PITTS:

We are really at the very cusp of it. I mean people keep saying that the 21st century is the genomic century, you know, the century of personalized medicine, and I think that's true, but you know just as we are at the very beginning of the millennium, so too I think we are at the beginning of understanding all the various things that the human genome can show us relative to appropriate medication. The first thing that we are seeing, which we are seeing right now is which medicines are not appropriate to be given to what type of people. Like, for example, there is a drug called warfarin, which is a blood thinner and it's a very good drug, but it's very dangerous to certain sub populations in the US and there is now a genetic test that exists that physicians can give their patients to understand, which patient should not be given this drug and in fact the FDA just recently changed the label of this medication to tell doctors that before they prescribe the medication, they should give their patients this particular test. So the science of gene testing is evolving, it's coming along slowly, and I guess another issue we talked a little bit about reimbursement a couple of minutes ago, a lot of insurance companies aren't sure whether they want to reimburse for kind of prophylactic genetic tests and I think ultimately they are going to realize that penny wise and pound foolish not to do that because not to pay for a gene test that could tell a physician, which drugs not to prescribe, which would allow patient not to have an adverse reaction or have to go through 2 or 3 iterations of medications and titrations, is not only going to save the insurer money, but it is also going to get the patient more healthy quicker.

DR. LARRY KASKEL:

If you have just joined us, you are listening to the Clinician's Roundtable on ReachMD, The Channel for Medical Professionals. I am your host, Dr. Larry Kaskel and I am speaking today with Peter Pitts, the cofounder of the Center for Medicine in the Public Interest and also Senior

Vice President for health affairs at Manning Selvage & Lee.

Mr. Pitts, you were talking about this new test. I am kind of interested in it because this is the first I have heard of it, what's the name of the test that you give to people before you put them on warfarin.

MR. PETER PITTS:

I am not sure of the name of the genetic test, but there is only one. In fact, there is a lot of information on the FDA website with big news on the FDA analysis because actually it was the first time the FDA ever put on the label of a medication that fact that a gene test is available and should be used and a lot of people, lot of physicians actually complain that this was the FDA beginning to tell the medical practitioner how to do their job, how to practice medicine, but I think ultimately it's the FDA's job to make the physician aware that these types of tests exists and that in a general risk benefit analysis situation, it's much more responsible to do a test rather than to just act on you know a past knowledge of the patient or past knowledge of similar patients because that as you know, every patient is different, everybody's biochemistry is different. Just responding to your experience as a physician while it's certainly very important, it can certainly be significantly augmented by a more precise genetic test.

DR. LARRY KASKEL:

What happens when drugs come to market too quickly, who suffers?

MR. PETER PITTS:

I guess the question is what does bring to market too quickly mean. I mean ultimately drugs are tested in clinical trials that is kind of anywhere from hundred to a few thousands to tens of thousands of patients, but at the end of the day, a drug will always have risks as well as benefits, and when a drug reaches the market and is used by tens of thousands or hundreds of thousands or millions of people, we learn more things more quickly, so the question of what does too quickly mean kind of leads you

down the path of discussing you know what type of risk is acceptable in various types of medications. Obviously you have a medication for say lung cancer, which is extraordinarily toxic disease, you accept a much larger degree of risk as you would for disease such as multiple sclerosis or diseases of the liver as opposed to pain relievers or allergy medications where you want a much lower degree of risk and a much higher degree of benefits so ultimately I think the question is not so much how are the drugs being brought to market too quickly, but do people understand that all drugs have risks. I think that you know Americans woke up the morning after the recall of Vioxx and they went Oh my God, you know, drugs have risks? Oh my God when did that happen? In any respect, both the industry and the FDA were victims of their own success and people assume that drugs in this country are so safe that they are completely safe.

DR. LARRY KASKEL:

Right, but they are drugs.

MR. PETER PITTS:

They are, and OTC medicines are the same. Even medicines you bought from the drugstore without a prescription has labeled they need to be followed and they have risks. I mean a lot of public officials, one senator actually said the day after Vioxx was withdrawn that the FDA should not approve any new drugs that have risks and I think that has showed me the tremendous amount of ignorance out there about the fact that drugs have risks as well as benefits and I think industry also you know bears a certain degree of blame for really underplaying the risks while you know painting a very rosy picture of the benefits. I think that we would all do much better to be much more honest about what these medications do and what they don't do and what risks they carry with them.

DR. LARRY KASKEL:

Well, I know on your website you talk a little bit about one of the more recent drugs that didn't make it,

it's called the Affairs of the Heart and you talk about torcetrapib and that was a drug that had an enormous amount of hype and it was suppose to revolutionize the treatment of atherosclerosis and it was killing more people than it was helping.

MR. PETER PITTS:

Well, the thing about torcetrapib is that it actually never made on to the market. It was a big drug, it was an experimental new drug by Pfizer and Pfizer looked at the clinical trials and at a certain point realized that it wasn't going to make it and they cut their losses and the losses, I imagine were pretty significant. It costs about a billion dollars to bring a new drug to market, but they saw the clinical trial, they saw that it wasn't going to be safe enough that the risk benefit analysis absolute was not in the proper order and they pulled their application so in this respect it isn't even the FDA being the watchdog as the pharmaceutical company itself looking at the results of clinical trials and saying it's not going to cut it and clearly that was a hard financial decision, but I think at the end of the day it was a very easy science decision and a very responsible one to make.

DR. LARRY KASKEL:

Well there is two other CETP inhibitors out there, what would you be advising these other companies that are still working on them?

MR. PETER PITTS:

Well, you know it's an important therapeutic category. Unfortunately, we are all becoming a nation of obese, diabetic hypertensives and you know these medications again unfortunately as all of us baby boomers age into the period of our lives where we are going to deal with this issues you know from a pharmacological standpoint, it becomes important if new medications comes to become available that are obviously different molecules and react differently in different people, so I think at the end of the day you don't want one drug to treat everybody because if one drug is on the market right now is good

for say 85% of the population, that I happen to be part of the 15% is not so good for, you know, I certainly want options and I want my doctor to have options. I want my doctor to be educated about which drugs to write for me personally.

DR. LARRY KASKEL:

Well, that makes me think of the new anticoagulant that I don't know if it's been approved or is about to be approved that is good for 80% and not great for 20%.

MR. PETER PITTS:

This is a new drug that Eli Lilly has an experimental drug called Prasugrel and right now there is only drug on the market for this is Plavix, which is a drug by Sanofi-Aventis, French drug company, and Plavix is a terrific drug. It's one of the world's you know most frequently prescribed drugs, but again you know if you have drugs that can be more robust and help a very large portion of patients, respond better, I think that's a good thing, but similarly as we are talking about earlier, you want to be sure that the people for whom it is not a good choice understand that's not a good choice and rather than going on that drug first, having adverse event being taken off the drug and put on a new drug with all the various hassles and intricacies and help complications that ensue, it's best to have a choice, but the doctor has to be able to make an educated choice and that means you know good solid clinical science, good experience with the drug, good journal articles, and good genetic test available.

DR. LARRY KASKEL:

Well, I would like to thank our guest Peter Pitts for joining us today.

MR. PETER PITTS:

Thank you very much, it was a pleasure.

DR. LARRY KASKEL

I am Dr. Larry Kaskel and you have been listening to a special segment on public policy on ReachMD, the Channel for Medical Professionals. We welcome your questions and comments here at ReachMD. Please visit our website www.reachmd.com which now features on-demand podcasts of our entire library. Thank you for listening.

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