

YOUR LEGAL RIGHTS

MEDICINE RISKS

GN Hello and welcome to Your Legal Rights My name is Greg Noble with the Wilentz, Goldman & Spitzer. Today I'm filling in for Chris Placitella who is on assignment. We apologize to those of you who are tuning in for the open public records act broadcast with Vince Maltese. That cannot be aired today and we apologize for that. Instead we're going to bring to you how do you find out the true risks about the medication you take. I am pleased to present to you that program and with me today is David Kane who's an expert in handling pharmaceutical cases and has a great background in that area which we'll tell you about and we're very pleased to have him and to be able to discuss these important issues with you today. Throughout the hour we will be taking questions from you. You can submit them by clicking on the appropriate interface. We do want to stress that we are going to give general advice today. We're going to be giving you an overview of some issues related to pharmacy law and issues concerning warnings on medications. We are not going to give you specific legal advice about particular issues relative to you. If you have a specific legal question, we encourage you to contact a lawyer who can help you with those issues and answer those questions. Again, we're going to be just be giving an overview today and sought of giving you the lay of the land about particular issues that can come up. So we encourage you to send us questions and I'll do the best I can to bring those up in the course of the discussion. If you want to watch this broadcast at a later date or share it with a friend, I understand that. In a few days this will be up on our website and you'll be able to click on it and view it at a later date. So we encourage you to do that if you find that it was valuable to you in some way. Again, we'll be with you for approximately 45 minutes to an hour. We encourage your questions. We'll be giving you general advice and not specific advice. And without further ado I'd like welcome and thank David Kane who is with us today.

DK Certainly Greg

GN I just want to say you for spending some time with us this morning and I'd like you to give the audience just the benefit of your background and your perspective in handling issues surrounding pharmacy law

DK Okay. Well first of all. I'm a licensed pharmacist in the state of New Jersey. I'm also an attorney at law in licensed in both New Jersey and Pennsylvania. Prior to practicing law I worked as a pharmacist for ten years. I worked in Community Pharmacy and in a number of other clinical settings, so I have a wealth of knowledge and background and experience that I rely upon on my prior work as a pharmacist in reviewing pharmaceutical claims. I think the added benefit is that I understand integrally what goes on behind the counter. What goes on within a pharmaceutical company, and combine that with the legal understanding we have with, you know, I'm able to assess claims from a unique prospective.

GN I'm glad that you're here because I have a sort of a very basic question to start with that I think may be of some value, just about how sort of the pharmaceutical industry has changed. I mean as a kid going to the local mom and pop pharmacist and having sort of a relationship with that pharmacist where if a question arise there would be no hesitation in bringing that to the pharmacist attention. Today, you mind can get sought of confused with all of the different options available to you once you have that prescription. There is, I understand there are internet pharmacies, there are the chains that we all see and it seems that the sought of the local mom and pop pharmacist where maybe you'd get some more attention and maybe would get more information about warning is not as emphasized as it used to be. So I'm wondering if you have general thoughts on that as sought as a starting point for our discussion today about the importance of getting to the right pharmacy.

DK Certainly, certainly. As most, as apparent to most peopled there is literally a pharmacy on every corner. And that relationship with the pharmacist maybe more important than you would think. With regard to the issue today, the pharmacist is the primary point or access to drug information and your relationship with that pharmacist is very important. Now, I'm not going to sit here today and say that an independent pharmacy pharmacist is more likely to give you more attention than a chain pharmacist. That relationship is up to the actual patient However, typically in independent stores where the volume may not be as high, they could sometimes spend more time with individuals, so again I go back the relationship that you may be able to strike with the pharmacist as being the most important element. Secondly there are specialty pharmacies. There are pharmacies that specifically with the elderly. In those instances they have facilities within their pharmacy. They may counters, the may have information and they may have also allocated their time differently to provide more information. The same thing with, there are some pharmacies that focus on preparing products for individuals who have different disabilities, so I suggest that you look at your own particular needs in picking a pharmacist and also you look towards a pharmacist where perhaps you can develop a working relationship with.

GN It sounds like if you have an interest in having a relationship with the pharmacist, you can do that even at a bigger place is what you're saying. But you have to initiate the relationship. You can't expect that a busy pharmacist at a particular chain you know, is going to be interested in spending half an hour with you. You have to go out and ask the questions and press the right buttons. Is that sought of what that would say?

DK That is 50% of it lies with the patient and the have to take the initiative. However, it is easy to distinguish the type of pharmacist that you're dealing with. Some pharmacists do not want to talk to patients and if you are a patient that needs that sought of interaction you will know at that point that perhaps you should go elsewhere.

- GN David, who is at risk in our modern age of taking a drug without really understanding what they're taking. Are there different groups in society that you run into that seem to have more of a problem?
- DK Well, Greg speaking generally because there are certain risks that, which everyone is at risk for. However, in general senior citizens are an at risk group. A lot of times their physicians don't necessarily explain to them the full scope of their drug therapy and they don't have a full grasp of many of the elements of their therapy that they need to know. Again, seniors in general may also experience side effects at a higher rate and because of this we seen an instant dynamic occurring. The people who need the information the most are the very population who are getting the least information and as a result of this they're experiencing an abnormally high rate of side effects and adverse drug reactions . In addition, certain impoverished communities don't have access to drug information. They may not have access to the internet. They may not have access to different community or medically oriented sources of information and those populations as well are at risk for not appreciating the type of reactions the drugs can cause.
- GN What are some of the resources out there for someone maybe was prescribed a drug and just wants, without having to talk to the pharmacist, without having to call the doctor, maybe they just want to get some more information about the product they are taking. Are there any resources out there, David, for sought of an everyday person to get a hold of and learn about what they're taking?
- DK Certainly. There are a number of resources and as Greg skipped over _____, without called the pharmacist or doctor, again, I recommend that those be the primary sources of information. But again, the internet is an extremely valuable resource. In addition, at a number of, there are a number of community organizations that provide drug information. But again, I think the primary source is the pharmacist with regard to that
- GN Do you see any trend with the FDA now, I would assume with the different administrations that come in and out and the changes, do you see a trend where it gets tougher and tougher to get a drug approved. During some periods it seems more lenient. Do you focus on those trends or is fairly regulated and standard throughout the years.
- DK Well, there are numerous trends Greg. And the trends they wax and the wane. Again there was a trend to streamline the process. But as he started to streamline the process he saw instances where perhaps this was not appropriate and we need to slow down. We need to further critique the drugs that we do allow through the fast process and in making slow down from other drugs. So it's a combination of both.
- GN Okay. David maybe you could help us understand the material that you're supposed to get when you go to the pharmacist and you get your prescription. We

hear things about contra-indications, warnings, adverse drug reactions, drug interaction, these are terms that I know put me off not having any pharmacy background, it may put off some people when you look to take a drug to help them get better and there's a list of warnings and interactions a mile long on the paperwork. What should we expect to get when we go to the pharmacist?

DK Well, when you go to the pharmacist there are two things typically that you will get. You will either get the actual package insert which the drug company provides to the pharmacist for drug information, or in most cases you will get a printout from the pharmacy which basically is an abbreviated version of that package insert which provides these contra-indications, these adverse drug reactions, these drug interactions. All of which mean something different, but often times people will get them confused. For example, a contra-indication. If you see the word contra-indication, that is a specific warning. That is the instances within, contained within a contra-indication are, are problems that are very likely to occur. For example, a certain drug may be contra-indicated for a person with a certain disease. So there is a relatively high certainty that if that person takes that drug, there will be a serious reaction or you know, or you just should not do this. Now, below the contra-indication you also see a list of warnings and warnings are more general. Warnings basically say that these things may happen. We warn you that perhaps you should use precaution in these areas. It's not as strong as a contra-indication and then there are two types of interactions. There's a drug interaction and then there's a disease interaction. And again, both of these two fall under the contra-indication category but also their own individual categories. And for example, a drug, drug interaction would simply say if you're taking this drug, you should not take this other drug because some specific adverse event could happen. A drug disease interaction simply says that if you're taking this drug and you have this disease, something you may be at risk for a certain reaction. And, lastly you will see a category called adverse drug reactions and this section warns you of problems that you can experience simply by taking the medication. Things that you should look for within your body after you've taken the medication that will basically alert you to stop taking it or to contact your pharmacist or contact the doctor.

GN Should you expect to see all of the indications and warnings that you just discussed every time you get something from the pharmacist or does it, can it vary by drug?

DK Well the first time that you do get a prescription you should expect to get this information from a pharmacy. Many times pharmacies do provide it on refills, however, they don't have an absolute duty to do that. But when you do get the medication you do you can expect to get that information. But it ultimately and most people don't know this, the pharmacist is the primary source for drug information and that's what I recommend people go to, but the physician's also have a definite to warn about the drug.

- GN And if you have questions it sounds like there, you should direct them towards the pharmacist at that point. Once you're at the cash register and you taking a look at the paper work, is that a good time to sought of ask the questions that you have?
- DK It's always a good time to ask the questions that you have. You can ask the pharmacist questions at any point, but if you do have questions about that particular information and the pharmacist is fully equipped to answer those questions.
- GN We have a . . . I didn't mean to look away earlier, I just, there's an interesting question that coming through that I just wanted to bring to your attention and the question reads "are there differences between US, United States approved drugs and drugs with the same name that someone can purchase through Canada and Mexico." Do you have any thoughts on that?
- DK Well, yes. Generally the drugs are the same. There are certain precautions, safety measures that our country takes with regards to drugs that cross the border and the concern is that perhaps we cannot safeguard these drugs although they are the same drug entity we cannot safeguard them if they're being distributed or marketed outside of our border, but generally the identical drug formulation, the drugs are identical.
- GN I guess you would recommend not going to Canada to get medicine when you can get it you know, in the United States under our government's approval.
- DK Well, I'm not going to answer that question (laughing) because there's been a lot of debate on that particular issue and you know our country is even divided. The senate is divided on whether we should or should not do that. I'm simply stating that our law does require certain safety measures we cannot necessarily assure if you do go to Canada on one hand, but on the other hand they have safety measures as well that many people believe are adequate.
- GN You mentioned earlier a package insert from the drug company.
- DK Yes.
- GN That goes to the pharmacist and it sounds like that can be passed on to the consumer, but not always. Is that . . .
- DK No, not always. There is a very limited group of drugs where the pharmacist has to give the package insert on each prescription. For example, with birth control, also with certain cholesterol medications the law requires that the pharmacist give the drug companies insert with those, but generally for 99.9% of the medications, the pharmacist does not have to give that insert and if you do want that insert you have to need to ask for it.

- GN But what are benefits of having that insert. I mean is that an insert generated by the drug companies marketing department that just sort of puffs up the product or is it useful information concerning warnings and adverse effects and so forth?
- DK Well there are pros and cons to getting that insert. First of all the insert is approved by the FDA and they critique the insert. The pros are that there's a wealth of knowledge on that package insert. It gives you a historical breakdown of the medication. It talks about every conceivable area that, that the FDA actually examined with regard to that drug. The cons are that there are exhausted lists of warnings and dangers and actually it causes a lot of apprehension in people who read these inserts and many times we find that people are actually afraid to take the medication when they look at all the information in the package insert. So, generally with most medications you defer to the pharmacist to let you know whether the more critical adverse reactions that you need to look for.
- GN Okay. David, what's a black box warning. It sounds scary. Can you tell us what that is and how that comes into play?
- DK Sure, sure. With certain medications there are dangers that are particularly harmful and when the FDA is enlighten to this they will require that a special warning be placed on the package insert or a special warning be placed in all the drug literature which actually appears in a black box at the top of the different forms of drug information in the package insert, in the PDR, in the drug box of comparisons and within this black warning, black box, you will see a specific warning that is basically letting you know that if you do this, there is a likelihood that death or serious injury may occur.
- GN Could you give us an example of just generically an example of what we're talking about.
- DK Certainly, certainly in some cholesterol medications for example, when the drugs came , first came to the market they had their contra-indications and their warnings that we previously discussed, however, through the post marketing surveillance it was realized that there was a condition called rabdomilosis that could occur and this is a potentially life threatening condition, so this information was placed in the black box to warn practitioners that you know if you give this medication in combinations with other medication in combination with another medication, this serious disease may occur so don't do that. In addition you'll see on many antineoplastic or cancer drugs contra-indications on giving these drugs in certain amounts. You have to, the black box warning may say you must adhere specifically to these guidelines or death or serious injury may occur. Those are two examples that we see quite frequently.
- GN We're going to talk about this in a couple of minutes as it relates to the pharmaceutical company's legal defense, but sought of generally speaking, what can you expect from your doctor about in terms of getting information about the drug that you're taking. How much has he or she been educated on the drug and

what can you expect them to know, more or less that the pharmacist, can you speak on some of these issues?

DK Sure, sure. Generally a pharmacist may have a wider scope of understanding on a larger group of medications, but physicians that specialize in a certain area may have specialized information about the drugs that they prescribe. The law requires that physicians carry the ultimate duty to warn an individual of the risks associated with taking medications. Pharmacists do not have that duty within the law, but within society we understand that the pharmacists are equipped to provide that information.

GN And what kind of liability does the drug company face if you know for example, if a doctor prescribes a medication without maybe giving the appropriate warning, the patient takes it, gets it from his local pharmacist and something horrible happens. What are sought of the legal issues involved and again in a general sense.

DK Sure, in a general sense, what we find is that with regard to a drug company, when something happens we initially look to see whether the drug company has fulfilled their duty to warn the physician. There is something in the law called the learned intermediary doctrine. This is a term that we use quite often but what this means is simply the drug company physician has the responsibility to warn and the drug company generally cannot be held liable for something that happens if they adequately informed that doctrine. Now our end the question then comes in if we do have a plaintiff that is severely injured we have to ask the question of whether the drug company actually warned the physician sufficiently.

GN How do they do that? How does the doctor become aware of the risks associated with a particular drug?

DK Certainly. When a new drug comes on the market the drug companies have drug representatives that will enlighten the doctors on the particular drugs and how they should use it and give them suggestions. Generally the drug companies spend an enormous amount of money to educate the doctors because it's the doctor that will prescribe the medication and increases their market share and drive their profits.

GN Is that a formal process in your experience as a pharmacist or is that more sought of an informal meeting or

DK It's very formal and very organized. The drug representatives from the pharmaceutical companies have a geographic location and they have to talk to every doctor within that location and they have relationships that they develop with these doctors and there's different sorts of seminars and it's a very tight relationship the drug companies attempt to form with physicians.

GN And I would imagine that in a case that you handle this exchange between the pharmaceutical company and the physician becomes you know, significant.

- DK What, I'm sorry
- GN You need to I know, go ahead, what kind of things do you look at in terms of that relationship and trying to understand how sufficient the warning was.
- DK Okay, with regard to the warning issue, we have to make sure the doctor fully appreciated what the drug company was informing them of. We also have to look at whether the drug company purposely tried to be vague in their warning or tried to track the warning in a way that wouldn't necessarily alert the doctor to some hazards with regard to the drug.
- GN What kind of liability can a pharmacist have in a case where someone takes a drug and has an adverse reaction?
- DK Well, I want to refer back to the black box warnings and this is where we see many of the incidents. If an individual experiences a severe reaction that causes hospitalization or death and that very reaction was in the black box warning that may bring liability to both the physician and the pharmacist. I mean the pharmacist at that point does have a duty to safeguard such obvious, safeguard the public from such obvious warnings and in those cases the drug company has actually fulfilled their responsibility to inform healthcare practitioners of that problem generally.
- GN So a pharmacist should be alerted when he or she sees a black box warning and probably due his or her best to communicate that to the consumer.
- DK Certainly.
- GN Even if its on you know paperwork it sounds like its, the consumer should be looking for that pharmacist to explain that to them as well.
- DK Certainly. If there's a black box warning, whatever that black box says the pharmacist cannot fill the prescription or should not rather, fill the prescription in a contrary matter.
- GN What kind of training does the pharmacist get when a new drug comes out. Is it a similar exchange between a representative of the pharmaceutical company, you know having a training seminar for the pharmacist?
- DK Well, its they do speak with pharmacist. Drug representatives often come to my pharmacy and we would have short conversations. The relationship is not, is not equivalent to that, their efforts are not the same with regard to a physician. But they do bring the pharmacy drug and pharmacist drug information. The pharmacists also have seminars that they must go to and there's different magazines and drug literature that come and when a new medication comes a pharmacist's general practice is to look at the package insert and become familiar.

- GN Okay. David what are there's sort of a lot we read in the newspaper these days about diet drug litigation and cholesterol medication litigation
- DK Certainly
- GN Um, antidepressant litigation. It seems to be newspapers every day. Can you list for us so we have to start with and we'll talk about each one the general hot areas that you see in drug litigation today.
- DK Certainly Greg. One consistent theme throughout each of these categories is that we believe there has been some failure to warn physicians of the particular adverse events that individuals are experiencing. It's about naming the particular drugs on this broadcast, there are several antidepressants where people are experiencing attempted suicide, depression, severe depression, or even withdrawal systems when taking these medications. And when we some of our research we felt that the drug companies were perhaps aware of the side effects and didn't adequately warn the physicians who could then adequately the patients is also an interesting category of a hormone replacement therapy medications. And with regard to this group of medications, again without naming the specific drug, there's particular information that leads us to believe some of the risks for stroke, for certain types of breast cancer were known to the drug company prior to them actually putting the warnings, or adequately putting the warnings on the package and we're finding a lot of woman who experience stroke, who experience different ischemic heart problems and also several forms of lobular and lobular breast cancer as a result of these hormone replacement drugs.
- GN Let me just stop you for one second David and we'll get back to the categories. I'm just wondering when some comes to your office whose been, whose health has taken a turn for the worst as a result of taking a drug and not understanding the warning. How are you able to get at what the drug company knew and didn't know and when it's applied to the physician. Is that through you know litigation experience or are those public records. How are you able as that individual's attorney to get at those critical issues.
- DK Well again, it depends on the drug, the approach has different forms but most of our research is public knowledge, but that public knowledge is very broad and that public knowledge can span different countries and different time periods. Generally the drug company is responsible for knowing about all the studies that were conducted on its drug and in numerous countries and if we find information that they should of known and that they did not communicate and that we're now seeing in this person that's an indication that perhaps there was a breach in their duty to warn.
- GN How important do you think it is having a pharmacy background and handling the cases, you know, that we've been, we've been talking about. I would imagine they give you a sought of an edge in handling these types of matters.

- DK Certainly. These cases are very medically labor intensive. There are often times we have to go through medical records and a lot of the literature that we have to review will say is conducted by PhDs and some of the top scientific minds in the world and then having that background enables me to comprehend the material rather quickly. Also as far as getting up to speed with regards to a particular drug, because they hardly have a base understanding of pharmacogenetics, pharmaceutical dynamics, pharmacology, it enable me to comprehend why a certain adverse drug reaction occurred and what the drug company from a medical prospective should of known rather than from a purely legal prospective.
- GN So we know what you clients can expect of you. What do you, what helps you in the initial phases of looking at a piece of litigation. What helps you get off to a fast start. What do you need to know from a client generally because we're not again, we're not giving specific legal advise today we're just sort of laying the ground work but what generally do you look at when Mrs. Smith comes to you and tells you a story of an adverse drug reaction that has harmed her critically. What do you need to know out of the gate.
- DK Well the first two things that I need to know, I need to know specifically the harm or injury that she is alleging, that she's complaining of and I need to know the medical proof that's establishing that injury. For example, if someone comes to me and they say that I've experienced depression because of this medication, I need to know whether there has been a medical diagnosis of that depression. Because it's hard, it's impossible to make a claim based off an individual's diagnosis of themselves. However, we need some sought of medical proof that the injury actually occurred. The second major thing is we need actual proof that you used this medication, because a lot of these medications sound familiar to another medication, there are different medications within a certain therapeutic group, so you actually need to identify the drug and the duration in which that person took those medications to make sure the incident and the drug coincide we can make the course of this link.
- GN And it sounds like you take it from there.
- DK And from there we do have some background questions that says other medications they've been on, their medical history and you know familiar history.
- GN We talked about briefly that you touched on the hormone replacement drugs and the antidepressants. Are there other categories of drugs that raise a red flag in today's market.
- DK Sure. There are certain categories of diet drugs, a lot times these diet drugs are associated with stroke or different heart abnormalities, there are certain pain medications that are also associated with stroke or hear attack and again you probably need to go to the website to see a list of these particular drugs and there are also a number of medical devices too that we do consider. As far as over the counter medications.

- GN How is this area different with an over the counter medication. Are the other warnings different. Are should the consumer be more at ease, less at ease. What are some of things you face with over the counter matters.
- DK Well first at all people need to know that the FDA does not govern over the counter medications, it's the FTC that governs over the counter medications and their making specifically. You also must understand the duty of the manufacturers with an over the counter medication is directly is to the patient or customer with regard to the warning. With the prescription medications the drug companies only have to warn the physician. However with over the counter medications they have the duty to adequately warn the public so then we can directly look at whether they adequately warn the public rather than whether they adequately warn the physician.
- GN And here's the question that I've always had and I'm glad to have you hear to ask you this, um, how does something a drug that was once a prescription drug suddenly become an over the counter drug. I mean you see this a lot with cold medications and fever medications, pain relievers, and things of that sought.
- ? Should we concerned when we take a medication that once was a prescription medication. Should we be concerned that maybe that maybe its stronger than an over the counter drug should be.
- DK Well we should be concerned about all medications that you take and I guess everyone reads the warnings. However, again this is a trend and this is the concern only lies in your diligence in looking at the warning and appreciating how you should use the medication. If the drug companies can show that you know this ___ would be distributed to individuals directly without a physician's supervision, then you know they're given the green light and as our society has evolved and the information has come to the forefront and to the public and its easy for a drug company to make the argument that this drug can adequately be given without physician's supervision.
- GN So I would imagine there's some time that has to go by before something actually prescribed becomes over the counter.
- DK Certainly. The drug companies do have to prove that you know, the public will not be at any extraordinary risk if this is distributed directly to them. That the safeguard of the pharmacist and the physician are not needed because we can adequately protect the people with warnings.
- GN What types of over the counter products raise a red flag in terms of the litigation out there, not that you know we're criticizing any particular product. Just the things that you see.
- DK You have these dietary supplements. We also have over the counter appetite suppressants which do raise some pharmacological concern with regard to how they cause the body to respond in different settings and again those areas where

we do consider the warnings on the products to see if the drug companies adequately warned an individual that perhaps if you're going to take this you shouldn't be doing this or this.

GN Okay, we have some, I think we have some internet inquiries and we'll see if David can handle those. I'm sure he can. Um, the first question is, is there a way for the public to find those black box warnings on their own? Maybe before they've prescribed the medications.

DK Certainly. If the public asks for the package insert, you will find it there. There's also the PDR, there's a book called drug facts and comparisons and also if you have access to the internet you can go to the FDA website where they have all the black box warnings for all the medications.

GN Terrific. We have some more questions. Can my pharmacist insist on a name brand drug because it has less side effects even if my doctor prescribes a generic.

DK Your pharmacist cannot insist upon anything. The pharmacist can suggest, you know, if they have a certain belief, but they do not have a legal right to impede upon your, upon your therapy. That lies solely with the physician. Sometimes we do see third party plans that make a suggestion to the pharmacist, to change your therapy and the pharmacist is entitled to their opinion, but they'd have no legal authority to do that.

GN There are no further questions from the public. I just wanted to thank David for spending some time with us this morning and again I just want to remind everyone that if you only saw part of the broadcast or want to view it on at a later date, it should be available on the website in a matter of days. I just want again thank David for his participation. I want to thank those who forwarded internet questions and we'll see you next time on Your Legal Rights. Thank you.