Johner Institute

Product Liability for Medical Devices

With Specialist Attorney Sonia Seubert, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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You, the listeners of this podcast, are very firm when it comes to medical device law and you know what needs to be done to bring compliant products to market.

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However, even with compliant products, it can be that patients are harmed and here, of course, these patients must also be compensated, and that leads us directly into the topic of product liability.

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Today I have Sonja Seubert as a guest with me.

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Hello Sonja, could you briefly introduce yourself, please?

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Hello, my name is Sonja Seubert and I am a lawyer and specialist lawyer for medical law.

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I have been dealing with medical devices since my approval and also delve into the liability of medical devices as well as compliance issues.

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And if I tell you correctly, you were also active in court for years, precisely in these questions.

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Yes, exactly, I was on the road in courts for over 5 years and very likely got to know almost all regional courts and higher regional courts in Germany.

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Yes, but then we still have to start with an absolute line and introductory question, namely the question, what is product liability anyway?

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Product liability includes all questions of liability for damage caused in connection with products.

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However, this now applies not only to medical devices, but to all products.

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Or that's how it is, the Product Liability Act has not been developed specifically for medical devices, but applies to all products that are on the market.

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ISO 13485 also uses the term product, but it does not only mean products, but also services.

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Understands the Product Liability Act,

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Is a concept of a product just as broad or does it only mean real products, i.e. physical products or non-physical products such as software?

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Exactly, so that's the case that the Product Liability Act only covers products, but they don't have to be physical, but software is also considered a product.

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What is also interesting is that a prepared kidney, for example, can also be considered a product.

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Yes, now we come to the somewhat difficult question.

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Who is liable here anyway?

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So, the question is probably of interest to many medical device companies now, because then we have the concept of economic actors.

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In other words, do we differentiate between manufacturers, between importers, between dealers and yes, who is the Product Liability Act now aimed at or who is liable for their products?

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So, the Product Liability Act is first and foremost aimed at manufacturers.

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but here there is also a small exception for the so-called quasi-manufacturers, i.e. if it is not one of the actual manufacturers who is recognizable to the outside world, but for example a supplier would be visible as a manufacturer without distinguishing himself as such.

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So that would be, for example, something in the old P.L.M.

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O.E.M.

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scenarios, because that would then be the

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P.

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L.

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M., i.e. the one who puts his label on the device, would that be this quasi manufacturer?

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That's exactly how it is.

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So this is a typical case that you know from practice, that P.

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L.

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M.

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times as an actual manufacturer then completely into liability.

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What is also interesting and important is if you as a supplier have perhaps also marked yourself accordingly to the outside world, but still the actual manufacturer

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is not recognizable now, you can also be liable as a supplier if you do not name the actual manufacturer here after a corresponding yes notification from the injured party.

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So in practice, it looks like this, for example, that a product is written on the product, that a supplier X.

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Y.

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has delivered a product without naming the manufacturer.

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Then the patient can

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the injured party then to supplier X.

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Y.

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and say, please inform me of the manufacturer, but if he does not answer within a month and is so he is then considered the actual manufacturer by law.

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Mhm, we're lucky that M.

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D.

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R.

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because we have relatively strict guidelines about what is written on the labels.

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Absolutely.

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Yes, that brings us straight to the next big point, namely the question of damage amounts.

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the fear of probably many manufacturers or, as we have just learned, quasi manufacturers, may be that they fear that their existence will be threatened if a damaging event occurs.

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What orders of magnitude are we typically talking about here?

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So, you can't name such a typical damage here.

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So, the damage is always quantified individually.

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If we have an injured patient, he must

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where his damage lies in concrete terms.

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So this is a bodily injury to a hand, yes then it has to be documented and proven accordingly and then you also look at what the damage is.

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So it is now just for the duration, i.e. so-called permanent damage, the patient is then also impaired in everyday life and above all in the profession, so

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does that of course also play a major role?

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Does this mean that someone who has an irreversible loss, for example who is unable to work and has a higher salary, then has a higher amount of damage than someone who typically receives a lower salary?

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That's how it is.

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So the physical damage, as a rule, you won't make any distinctions now.

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But the so-called loss of earnings,

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is quantified concretely by what the person has earned and also what he would have earned until his retirement age.

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That can go into the 1000000, right?

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Absolutely, I have also looked after such cases.

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What will it cost in the worst case, i.e. if someone dies due to product damage?

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Of course, it is very bad when someone dies.

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It is a loss that

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cannot be repaired.

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Nevertheless, it is not a high damage in the sense of damages.

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As a rule, only compensation of 10,000 euros is eligible here.

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You probably couldn't imagine that in the USA.

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I can.

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So in the U.

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S.

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A.

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it really all looks quite different, especially because you now take into account not only this civil law claim, so to speak, but also the criminal law.

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So the manufacturer is also to be punished additionally in America.

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That does not exist in our civil law claims.

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When it comes to such sums right now, the question naturally arises as to who has to prove what to whom.

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In this context, I have also used the term

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reversal of the burden of proof.

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Could you introduce us a little bit to this mechanics, who has to prove what to whom, so that we can ultimately come to this compensation, perhaps using the example of, yes, perhaps an implant?

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So in the

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Code of Civil Procedure, it is generally regulated that the person who asserts his claim must also prove everything.

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Of course, this would mean that the patient would prove the damage, the error and causality.

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Here, however, one speaks of so-called reversal of the burden of proof, since the injured party is indeed

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must prove the damage and also the defect, but not a possible breach of the manufacturer's duty as such.

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So, I'll try to reproduce that in my own words.

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So, if the patient were to say, I have damage because the implant is broken, for example, and I think that the damage is obvious because you have to operate again and that the implant is broken, you can probably prove it quite well.

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Now, however, he would no longer have to prove that the

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The manufacturer is to blame for the fact that the implant is broken, but he would not have to prove the reason, it would then be the manufacturer who would have to prove the opposite.

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Is that true?

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That's more or less how it is, so of course he has to prove certain clues as to why there is an error.

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So if the prosthesis is broken, then you would definitely see here that something was not in order.

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but since there is also an alternative to this error, he has to present concretely why he thinks that there is a manufacturer defect.

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But it is actually the case that the manufacturer now has to prove or exonerate himself that his product was in order.

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The patient does not have to prove this.

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I imagine this is now quite difficult with other products.

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So with a broken implant, I think it's somehow more obvious.

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But if, for example, you think about such an electrosurgical device and the patient has some internal bleeding afterwards, perhaps because the coagulation did not work or internal burns, then I imagine it would be a bit more difficult to prove that it has anything to do with the product at all.

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Or am I mistaken?

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In this constellation with the electrocauteries, it is already the case that you have to draw a difficult line here, difficult to draw a line to the application error, because of course it may be that the doctor has made a mistake here.

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But if, for example, the doctor assures us that he has used everything as usual and he cannot explain to himself what was going on, then this is what is going on.

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already a lot for a product defect and in this case the manufacturer has to exonerate himself and prove that a product was also in order at the time it was placed on the market.

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O.

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K.

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and then we are at the reversal of the burden of proof.

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That's how it is.

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Yes, what do you recommend, what should manufacturers do now, except, of course, to develop their products as safely and compliantly as possible.

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So the manufacturer should above all

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also monitor the market so that it always stays up to date with the state of science and technology.

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He has to see whether the products don't need to be further developed or improved and to give a certain patient safety and also user safety and to document everything in particular.

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So I think that if someone has a reasonable technical documentation, then he shouldn't be afraid, because that's usually done by the P.M.S.

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So it's a duty

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von dem P.M.S.

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yes.

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Mhm, so here again the importance of Post Market Surveillance, which you mention here and there is the M.D.R.

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has already become very, very granular as far as this requirement is concerned and as far as the M.D.R.

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I probably also gave us that was your recommendation to take out appropriate insurance.

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Absolutely.

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So of course you can't insure yourself against intent, but especially if something unexpected happens, you can of course also insure such damage and that is highly recommended.

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Yes, we have been talking about product liability all along.

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What regulations are hitting here now?

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So which laws would you have to deal with, where would you have to read if, for example, you want to find out more details?

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So, if we want to look here, we look at the Product Liability Act.

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That's the A.

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and O.

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product liability.

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And of course, we can also look at our national standards such as Section 823 of the German Civil Code (BGB) regarding tort liability.

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K., i.e. for all medical devices with standards pre-loaded, this does not mean the international harmonized standards, but in this case a national law.

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Yes, for all those who want to know more about it, Sonja Seubert's contact details can be found as always in our show notes below.

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There is also a note again on the topic of post-market surveillance and also how it can be automated, because this constant surveillance is of course also a repetitive process and there is a relatively large amount to automate.

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Dear Sonja, thank you very much for being there.

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Thank you very much on my part.