Johner Institute

# Minimizing (medical) Product Liability Risks

With Prof. Dr. Boris Handorn, Prof. Dr. Christian Johner

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## Transcript

00:00:03 Speaker 1

Yes, greetings.

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Thank you very much for the invitation.

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Yes, that was the case more than 20 years ago.

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I was in the chair, I also did my doctorate there and originally come from the field of private international law, conflict of laws.

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So this means, according to the question in international situations, which law is actually applicable,

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And then I wanted to go into practice and thought that this is actually a nice topic to continue in practice and I came up with the idea relatively quickly that product liability law in particular has the advantage of selling products all over the world, you have supplier components from all over the world, so they have international issues.

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And so it then offered to go into product liability law, into international product liability.

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And so I started with these pathological cases over 20 years ago.

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So, if we start at the top and in general, when we talk about liability, we are talking about civil law.

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So, always the question, how much does the fun cost?

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It's all about money.

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For damages, for compensation for pain and suffering, for rescission.

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And if we zoom in a little further, we have the question: Actual contractual liability and non-contractual liability?

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When it comes to contractual liability, we still talk about warranty today.

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The term warranty has existed in the law since 2002, but not since a modernization of the law of obligations, but.

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Lawyers and practitioners still know what is meant by this.

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By the way, we are talking about liability for material defects today.

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That is, that is the question.

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what do I owe under contract law for defective goods and I always have that with my contractual partner, always bilaterally, whether it's with my buyer or with my seller.

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Warranty, this can perhaps be distinguished from the warranty from the liability for material quantities, warranty is something that I voluntarily give on top, certain durability guarantees against rust penetration for the next 10 years and

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When we talk about product liability, incidentally also about producer liability, which are 2 aspects again in the narrower sense, then we regularly understand this non-contractual liability.

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This means that someone is harmed by my product with whom I never had a contract.

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The patient is harmed by a defective medical device.

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How am I liable and under what conditions am I liable for these damages?

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I have just mentioned this fine conceptual distinction between product liability law and producer liability law.

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Let's start with the older one, the producer liability, as the name suggests, is linked to misconduct on the part of the producer, the manufacturer of a product.

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He speaks of so-called traffic safety obligations,

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they actually come from the very classic so-called tort law.

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This is national law in Germany, Section 823 (1) of the German Civil Code (BGB), general clause in tort.

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And there the case law has developed the so-called producer liability over decades, which is ultimately

about the fact that I, as the injured party, no longer have to prove fault, but the fault is presumed.

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Otherwise, I still have to prove that the producer has violated a duty to ensure road safety, for example that has developed poorly.

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Product liability in the narrower sense is more modern and this is then also shaped by European law, namely through the so-called Product Liability Directive.

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No one asks about fault anymore.

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This is a so-called strict liability or, as it is called in Anglo-American, strict liability.

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This means that I am liable for a product defect and that is why it is called product liability.

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and here, too, there are development errors, instruction errors, production errors.

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But that is the framework that is being opened up and we will come to this, the previous Product Liability Directive within the E.

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is from 1985 has been implemented in Germany in the Product Liability Act and just at the end of last year it came into force, a new product liability directive that will keep us busy for the next few years.

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Yes and yes.

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Like any EU directive, the Product Liability Directive must be implemented at national level.

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There is a transitional period of 2 years, which ends on 9.

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December 2026.

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This means that now, in the remaining almost one and a half years, there will actually be a lot of action at the national level in Germany as well.

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new legislation has been drawn up and this will lead to the Product Liability Act being completely rewritten or completely amended, because there are a lot of changes coming in.

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And it is sometimes a bit difficult for non-lawyers to understand why, if I have such a strict regulation, why do I still have something like producer liability next to it, is simply because the strict product liability is relatively strongly channeled.

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For example,

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currently still excluded after 10 years after a product has been placed on the market.

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After that, product liability no longer applies, but producer liability still applies as long as a product is potentially dangerous on the market.

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So in short, I have narrower requirements in the stricter liability and if I then fly out of product liability, then possibly the requirements of producer liability, which

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which are less strict, but may then have a wider and longer effect.

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Basically, what remains?

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So the principle remains that I am liable for product defects regardless of fault and who is liable.

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On the one hand, there is the manufacturer, but there are also suppliers of defective components, given

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if necessary, also the importer, although he did not manufacture the product at all.

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But if I import a product from outside the EU, the principle is that a liability subject should be within the EU.

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What is new is added, which by the way we have learned from the M.D.R.

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from Article 11 is the liability of the authorised representative.

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It is now being generalized

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and also applies to all other products via the Product Liability Directive.

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So the Product Liability Directive applies to all kinds of products, including medical devices, and the authorised representative is added as an additional subject of liability, so to speak.

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But as I said, nothing new in the medical device sector, but that is the basic idea and it depends objectively on whether a product

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be it at the design level, be it at the manufacturing level or at the instruction level, i.e. instructions for use, correspond to the state of science and technology at the time of placing on the market.

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That is the principle that will remain in principle.

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There are some innovations coming and

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can also say, tightening for the manufacturer's side.

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Roughly speaking, it is now clear that software is also a product in the sense of product liability law.

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This has actually been controversial so far.

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It is also further regulated how certain interfaces in the I.O.T.

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area of liability law.

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Even if I integrate certain digital services into my products, how am I liable for them?

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The catalogue for the question of when it is to be assumed that a product is defective is now being significantly expanded.

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And here, too, it is clearly emphasized by the legislator that regulatory compliance or regulatory non-compliance with product safety requirements, such as the M.

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are clear indications of a defectiveness of a product.

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Yes, that means that the dovetailing between product liability law and regulatory compliance is emphasized much more strongly.

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Eliminate, I wouldn‘t go that far, but mitigate and minimize as far as possible.

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And indeed, I always see it as a great opportunity to say when I

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on the compliance side, then I am also quotable and can then disclose, I have done everything right on the product safety side.

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Of course, it is an immense argument, if I am sued and are sued for product liability damages, that I can very well go on defense here.

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You have to keep in mind that there are still 2 very important points that come with the new Product Liability Directive.

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These are

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Disclosure requirements for potential evidence.

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This is a claim that a plaintiff will have in the future under the Product Liability Directive.

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This means that I will be much more transparent anyway with my technical documentation, with other information, for example about P.M.S.

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Data of my product in the field.

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This means that there are disclosure obligations here.

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And these are coupled with so-called facilitation of evidence.

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And among other things, it makes it easier for the plaintiff to prove that if I, as the manufacturer, do not disclose or do not disclose enough documents, it is suspected that my product is defective.

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And there are also other presumptions of proof, facilitations of proof, which go to the effect that if I have violated certain regulatory requirements, it is presumed that my product

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is defective under certain circumstances.

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And it can even be assumed that there is a causality between a product defect and the damage if I have very complex products.

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Incidentally, innovative medical devices are mentioned in the recitals and AI applications.

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If you now have an innovative medical device with AI, you fall into this particular complexity.

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That is, please be aware of:

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they become more transparent, they are more or less forced to disclose documentation due to the effect of such shifts in the burden of proof, then it makes a lot of sense to think about it today, because it is the mistakes and the processes of 5 to 7 years that they have to tackle today.

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And if they're quotable and there's where we can say it, please here, we've done everything right.

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this is the best defense it can have in such a case.

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Conversely, if this documentation is not available, there is a relatively high probability that you will lose the case for this reason alone.

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Right, if you now think about what can you do to prepare for the new product liability law, in fact, make sure that you close the gaps, to look at what product liability guidelines do I have,

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It is possible that something is shifting, especially in the software sector, because here my product is now moving even more into the focus of product liability law.

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The second point is also as an established manufacturer, check whether your product liability risks are shifting with regard to your compulsory insurance under Article 10 (16) MDR.

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That means you need to have a

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Product liability risk coverage and I would recommend everyone to take a look at it, is this postponed by the new Product Liability Directive and perhaps also the following point or Product Liability Directive, for example the periods under which I can be liable, they can shift depending on the product.

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I said earlier, 10 years after the harmful product was placed on the market,

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If so-called, I'll call it latency damage, i.e. damage that usually does not occur within 10 years, is discovered, this can be extended up to 25 years of product risks.

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I'll talk about biocompatibility and cytotoxicity.

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That is, if I have typical risks that develop over long periods of time in the first place,

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this also shows, if I have appropriate products, my liability risk and I just have to see if I am sufficiently insured for it.

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In any case, please take a preventive look at it in the near future.

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On the one hand, of course, if a liability case has actually already occurred, i.e. despite all preventive advice, still in out-of-court uncourt disputes.

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can be on the one hand, in the defense of concrete product liability lawsuits, for example, I have carried out a recall in the field and then the wave of claims builds up, i.e. from patients or even from health insurance companies.

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Another case is the situation where I have received a potentially defective component, which would be recourse in the supply chain.

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That means I argue with my contractual upstream supplier about who

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who pays for the recall, who pays for potential claims for damages in the field.

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And the further aspect, and I believe that it is precisely from these pathological cases, which have also been cared for for over 20 years, that I can draw the experience, so to speak, for simply preventive counselling.

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That is, what points do I have to pay attention to today, what can be done in

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really hurt for many years and how can I turn it off quite easily now and that starts with the development of a product, with the question of how to build up my technical documentation and what points will I have to think about here soon.

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So in my experience, if you face these risks, you can minimize the risks in the future, which will then become much more expensive.

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The most expensive thing is if you simply ignore it, because then you stand there and have nothing to defend yourself.

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I was always very happy.

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Thank you very much.