Extract from Oireachtas Transcript Sept 28 2023

Ms Eilish Hardiman is CEO at CHI. Her testimony at the Oireachtas Committee on Health on September 28th 2023 attempted to convince the committee that the surgeon knowingly implanted a non-medical grade device.

We have compiled extracts from the committee that indicate that Ms Hardiman met Mr Connor Green and Professor Damien McCormack in February 2020. They told her about the spring system and they asked for her advice as CEO on the administrative process.

She says she never received the letter from Mr Connor Green. This letter was given to An Taoiseach by Deputy Mary Lou McDonald.

Mr Greens letter to Ms Hardiman is clearly a summary of a meeting he and Professor Damien McCormack had with Ms Hardiman in February of 2020 where he told her about the spring device. It is not intended to give her new information but to summarise the meeting in a way to document it for the record.

It is important to note that no where in Mr Green's letter does he mention a non-medical grade device. We have obtained a copy of this letter and it can be read on our website. It is written in the assumption that it is a medical spring but he is asking Ms Hardiman the processes around bringing in the device safely and appropriately to CHI.

CHI failed to check the medical grade of the spring. CHI failed to subject the spring to the administrative process Mr Green asked Ms Hardiman about since he did not know what to do. CHI failed to provide Mr Green appropriate equipment to do his job. CHI failed children in their care and Ms Hardiman as CEO is responsible for CHI.

Ms Hardiman's responses avoid acknowledging that Mr Green believed he was implanting a medical device.

It seems that Ms Hardiman is scapegoating Mr Green for her failure to appropriately give the guidance he asked for.

The following testimony shows how Ms Eilish Hardiman and Dr Paula Kelly try to scapegoat Mr Connor Green. Saying it was only the surgeon responsible and there is no process issue.

But Senator Martin Conway gets Dr Allan Goldman CMO to admit that the system is flawed and Dr Goldman has no idea if all devices across CHI in other specialities are medical grade.

It is clear that CHI failed and are trying to blame Mr Connor Green

> **Senator Martin Conway:** That is grand and I totally accept Dr. Goldman's bona fides on that but I am trying to find out whether there have been other instances. I cannot take the witnesses' word that there have not been, simply because this has happened in spite of all their cross-references, checks and balance and so on. They cannot definitively tell me there are not other devices that were not of medical grade used on children.
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> **Dr. Allan Goldman:** All we can say is at this stage we are completely unaware of any other devices. Nobody can say 100% on anything. It is terrible. We put our hands up. We want to learn and make this better and make it never happen again.

The following shows how Ms Eilish Hardiman CEO and Ms Paula Kelly try to scapegoat Mr Green.

Ms Eilish Hardiman CEO CHI is questioned by Deputy David Cullinane and refuses to say that she did not discuss the use of the spring distraction system indicating on February 20th 2020 at a meeting with clinicians.

I need to move on now to my next question. Did Ms Hardiman attend a meeting at some time in February 2020 that was attended by a number of consultants, one of whom is the subject of the Medical Council complaint at the moment, at which the issues of experimental techniques and the use of the metal rods referred to earlier and the spring-assisted techniques that have also been mentioned were discussed?

Ms Eilísh Hardiman: I am conscious that CHI is not in a position to name the individuals and we need to be very careful because I am in the HR processes on that.

Deputy David Cullinane: I did not name the individuals. I have asked if Ms Hardiman attended the meeting.

Ms Eilísh Hardiman: Yes, I did attend a meeting. I know the committee has shared with me the emails about that. It related to a different system. I am prepared to talk about this because it is not related to the investigation under way and I cannot and do not want to preclude any outcome of any investigation. Everybody is entitled to fair process here.

Deputy David Cullinane: I see that. I asked my question so that we have absolute clarity, because there is a lot of information now coming into the public domain, from the CHI's perspective. Obviously there will be an external review. I am simply asking Ms Hardiman, regarding the issues she discussed, including the high-risk techniques and use of the metal rods, to confirm she was not involved at any point in any discussion, at formal meetings, of those issues in terms of their use.

Ms Eilísh Hardiman: I can say that I have meetings all the time with clinicians and we talk about innovation. That is normal. We are very supportive in Children's Health Ireland.

Deputy David Cullinane: These are high risk, as Ms Hardiman pointed out. On the issue of high risk and metal rods, was Ms Hardiman involved in any discussions relating to that issue?

Ms Eilísh Hardiman: I am prepared to say that I was involved in discussions about MAGEC rods because I was very clearly aware of the field notice around MAGEC rods at the time.

Deputy David Cullinane: In her opening statement, Ms Hardiman mentioned "metal rods" and "high risk". I am asking her about that issue. Was she involved in any discussions with clinicians and others at any point on that issue? That is the terminology she used.

Ms Eilísh Hardiman: That is subject to an investigation with which we will fully cooperate and-----

Deputy David Cullinane: Ms Hardiman has not answered my question on whether she was involved in any meeting on those issues, which for me is fundamentally important.

Ms Eilísh Hardiman: I am being clear, if I may, that I was involved in a meeting around MAGEC rods, which are separate, because of a result of a field notice.

Deputy David Cullinane: Ms Hardiman cannot say "No" to me. I have asked her a question on the issues that she raised about the use of metal rods and the high risk nature of them and whether that was also something that she discussed or was part of discussing in formal meetings. Ms Hardiman cannot tell me "No". I have asked her four times and she still has not said, "No, categorically I was not."

Ms Eilísh Hardiman: That is because if it is in relation to the devices, which are non-medical grade devices, that is part of an investigation. I am absolutely willing to partake in that investigation and I will answer all the questions through that process.

Deputy David Cullinane: I am not satisfied with those responses at all.

Ms Hardiman CHI CEO is then Questioned by Deputy John LaHart. The deputy again asks Ms Hardiman about the meeting with clinicians on February 20th 2020. Ms Hardiman tries to deflect by implying that the spring was research that should have been discussed with research teams. It is clear from Prof McCormacks interview with Meave Sheehan in the Sunday independent that this was not research it was a bespoke solution for patients. The surgeons were not trying to develop new techniques but were using novel techniques they had seen at international conferences.

Ms Hardiman goes on to say that she does not approve off label use in CHI. This is dishonest since 80-90% of medications used in children are off label and nearly all surgical implants used in children are off label.

Ms Hardiman's statement refers to alarmingly unapproved non-medical grade devices. Did orthopaedic consultants or consultants ever seek advice from Ms Hardiman or senior staff within CHI on the use of alternative devices, technology or techniques?

Ms Eilísh Hardiman: We have discussions with clinicians all the time in relation to this. It is not unusual to talk about research, about doing something differently and what research has been done. That is the world that we live in.

Deputy John Lahart: I get that, but I am talking about the use of specific techniques or pieces of equipment.

Ms Eilísh Hardiman: We tend to approach that at a broader level, certainly, where I would be involved. We discuss the plans for the services with the clinical directors.

Deputy John Lahart: In response to Deputy Cullinane, Ms Hardiman mentioned discussions specifically about the MAGEC rods. She has, therefore, been approached about specific devices.

Ms Eilísh Hardiman: A field notice on the MAGEC rods was issued by the company, so we were responding to that and making sure that everything was in place.

Deputy John Lahart: Was Ms Hardiman ever asked for her advice, as CEO, by consultants, orthopaedic surgeons or surgeons in relation to the approval of off-label or experimental techniques?

Ms Eilísh Hardiman: I am prepared to say that I have never approved off-label-----

On questioning by Deputy Róisín Shorthall Ms Hardiman claims to have no recollection of the part of the meeting relevant to the spring. She also refers to the discussion being about approval of a non-medical grade device despite being corrected multiple times by Deputy Shorthall who sticks to

the facts that Ms Hardiman was asked for guidance on a non-conventional treatment. Ms Hardiman also admitted that she is responsible for the failure by standing aside of the investigation.

Ms Eilísh Hardiman: My office. I am being very careful. I stepped back from all involvement in the commissioning and from all involvement in the investigations relating to this once I became aware that there was a letter to me implying I was involved. For good governance, I wanted to ensure the separation and that there would not be any conflict of interest.

Deputy Róisín Shortall: Ms Hardiman has not stepped back.

Ms Eilísh Hardiman: I have. I am not involved in the setting up of the investigations.

Deputy Róisín Shortall: Press statements were issued on Ms Hardiman's behalf denying this course of events.

Ms Eilísh Hardiman: I want to be clear. I am talking about what happened once I became aware of the investigation. To be honest, I was just being open. I have not received this letter and I have no evidence of receiving this letter. I have absolutely not approved non-medical devices-----

Deputy Róisín Shortall: I did not ask if Ms Hardiman approved it. I did not ask that. I asked if Ms Hardiman had a conversation with any consultants about the use of experimental techniques in relation to this very small group of principally spinal muscular atrophy, SMA1, patients.

Ms Eilísh Hardiman: I have gone back and looked at it. I have no recollection of that. In my notes, it was about Magec rods. That is what I discussed.

Deputy Róisín Shortall: Is Ms Hardiman saying that at no point was she told by any consultant about a proposal to use these springs?

Ms Eilísh Hardiman: I have absolutely no recollection of that. I would like to co-operate fully with investigation and ensure that the facts-----

Deputy Róisín Shortall: No. I did not ask about that. Is Ms Hardiman saying she had no information about a proposal to use these springs?

Ms Eilísh Hardiman: This letter is claiming that-----

Deputy Róisín Shortall: Sorry, I am just asking if this is what Ms Hardiman is saying. Is she saying that she was given no information about the use of these springs prior to their implementation?

Ms Eilísh Hardiman: I have no recollection of a discussion about that prior to it actually being implemented.

Deputy Róisín Shortall: Will Ms Hardiman stick with the question I am asking. Is she saying that she had no discussion with any surgeon about the use of these springs?

Ms Eilísh Hardiman: I am saying that I have notes on everything of a meeting that was held.

Deputy Róisín Shortall: Ms Hardiman has notes of a meeting.

Ms Eilísh Hardiman: It will be part of the investigation.

Deputy Róisín Shortall: No, sorry-----

Ms Eilísh Hardiman: Please, Deputy. What I have in there is around the field notice, which is what I understood-----

Deputy Róisín Shortall: I am sorry but that is not what I am talking about now. I asked Ms Hardiman a question. I will ask her for the fifth time. Is Ms Hardiman saying today that she had no discussion with any consultant about the possible use of these springs?

Ms Eilísh Hardiman: I cannot remember any discussion. I definitely have a recall of a

Deputy Nessa Hourigan outlines the ridiculous nature of Ms Hardimans claims that a surgeon just walked into theatre with a spring

Deputy Neasa Hourigan: I want to finish up on a question to Ms Hardiman. I note the

reports are from the medical establishment and I am not from the medical establishment. They are very data-driven and focused on outcomes in terms of infection rates and so on. I do not know medicine but I know procurement very well, and there is very little about procurement. We have talked a little today about public trust and about the difficulty for the families in getting information. It is incredibly opaque to me how somebody walked into a theatre with a non-medical device. I am not asking about the specific person. I am trying to understand who in CHI is in charge of procurement - not the individual person, but what is the title. How does it happen? I imagine that in a controlled situation where there is a controlled device that has a reference code, that is delivered through a controlled piece of procurement to the hospital, it is then stored within a controlled environment, as a medicine would be, it is packaged in a sterile package and it is delivered to the theatre in controlled circumstances. What has been described in the press this week is somebody putting a spring in their pocket and walking into a theatre. I do not understand how that level of opaqueness is allowed in this process. I do not understand how that device was walked into a theatre, in theory. Can the witnesses advise me how a device is walked into a theatre that is not packaged or CE-marked? I am sorry to sound completely naïve. I just do not understand. In theory, how would it happen?

Senator Martin Conway points out that clearly CHI do not have processes in place to ensure appropriate devices are implanted. Dr Paula Kelly tries to deflect from this fact by saying the surgeon should have known not to implant it. But it is clear that the surgeon thought it was a medical spring and no where in the letter does it say otherwise. Dr Paula Kelly also tries to scapegoat Dr Connor Green for CHI failing.

Senator Martin Conway: I know it is a very unusual event but there can be other unusual events. How can Ms Hardiman categorically assure people there are not other unusual events?

Ms Eilísh Hardiman: Because we have a quality assurance process in our decontamination units. That process can pick up-----

Senator Martin Conway: What I cannot get is this: those quality control mechanisms were in place before this happened, yet it happened.

Ms Eilísh Hardiman: It did. That is part of the-----

Senator Martin Conway: How can Ms Hardiman definitively say other issues of a similar nature have not happened?

Ms Paula Kelly: We apologise for what happened. It is indefensible. It would be up to the surgeon. There is a code of practice whereby each surgeon would know not to implant a

non-medical grade device. Once we became aware, email correspondence went around to all theatre users, reminding them there is no permission from anyone to implant non-medical grade devices.