

Defective medical devices: Analysing the role of the criminal law in the PIP breast implants scandal

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1. Introduction

The criminalisation of healthcare malpractice has been much debated and criticised in recent years.¹ Research in this area has led to arguments that the criminal law is not always effective to respond to healthcare malpractice by criminalising individual professionals.² Some have argued that the criminal law should only be used to prosecute the most serious cases of healthcare negligence showing a high level of moral culpability and which reflect a deliberate or reckless state of mind.³ While new offences of ill-treatment and wilful neglect have been included in the Criminal Justice and Courts Act 2015 in England⁴, so far the criminal process has not played a major role in seeking to respond to healthcare failure.

France has been known for using the criminal law more widely than England in cases of healthcare malpractice and in particular healthcare scandals such as the HIV-contaminated blood scandal or the Human Growth Hormone scandal.⁵ These healthcare episodes saw the use of negligence offences as well as fraud offences against doctors and health officials. It should be noted that French criminal law has gone far beyond what we would see in England in relation to prosecutions of individuals for ‘medical manslaughter’ and often plays a major role in holding healthcare organisations to account. Nevertheless, it is strongly argued that the use of the criminal law in healthcare scandals in France has achieved little to prevent further healthcare disasters and preserve healthcare safety.⁶

More recently, rather than the state and public health institutions, private laboratories and companies are the new protagonists of healthcare scandals. These episodes seem to show a more culpable state of mind which goes beyond mere negligence. This paper focuses particularly on the role of the criminal law in the very recent Poly Implant Prothèses (PIP) scandal in France. PIP was under the control of TÜV Rheinland and *Agence française de sécurité sanitaire des produits de*

¹ C Erin, S Ost (eds), *The Criminal Justice System and Health Care* (Oxford University Press 2007); AM Farrell, M Kazarian, ‘The Role of the Criminal Law in Healthcare Malpractice in France: Examining the HIV Blood Contamination Episode’, in D Griffiths and A Sanders (eds), *Medicine, Crime and Society* (Cambridge University Press 2013) 265-279; O Quick, ‘Medicines, mistakes and manslaughter: a criminal combination?’ (2010) 69(1) *Cambridge Law Journal*, 199-201; M Kazarian, D Griffiths, M Brazier, ‘Criminal Responsibility for Medical Malpractice in France’ (2011) 27(4) *Journal of Professional Negligence*, 188-199.

² AM Farrell, M Kazarian, above n1; M Kazarian, D Griffiths, M Brazier, above n1; M Brazier, A Alghrani. ‘Fatal Medical Malpractice and Criminal Liability’ (2009) 25(2) *Journal of Professional Negligence* 51-67.

³ M Brazier, A Alghrani, above n2; M Kazarian, D Griffiths, M Brazier, above n1; O Quick, above n1 at 187.

⁴ The new offences have been included in Section 20, Criminal Justice and Courts Act 2015.

⁵ M Kazarian, *The Role of the Criminal Law and the Criminal Process in Healthcare Malpractice in France and England*, University of Manchester (PhD Thesis), 2013, 127.

⁶ Ibid at 195.

santé (Afssaps)⁷, two regulatory institutions whose role was to ensure that products delivered by PIP were safe. Yet, PIP directors and employees managed to deceive these regulators and use low grade industrial silicone in breast implants. Five PIP directors were convicted of *fraude* (fraud) and *tromperie aggravée* (aggravated deception) in one set of proceedings. In a second set of proceedings, PIP directors are being prosecuted for *blessures involontaires* (involuntary wounding). The scandal affected approximately 400000 women with PIP implants around the world.⁸ Even though there is a higher rate of rupture in PIP implants than in other breast implants, no evidence has been found of a link between rupture of PIP implants and cancer or of a significant risk to human health.⁹ However, ‘the possibility of health effects cannot be ruled out’.¹⁰

This paper seeks to analyse the use of the criminal law in the PIP episode. It has been argued that in the context of healthcare malpractice, only reckless and deliberate behaviour should be criminalised.¹¹ As will be shown, PIP directors knowingly manufactured and supplied defective breast implants, in breach of safety regulations, and also deliberately put patients at risk of harm, which amounts to deliberate conduct. Thus it will be argued that PIP directors should be criminalised on two grounds: deception and deliberate endangering. Like in previous healthcare scandals, victims seemed unimpressed by the use of *tromperie* in the PIP episode, and are asking for the use of negligence offences in addition. It should be noted that French criminal law offers a wider range of criminal offences which can be used in cases of healthcare malpractice than English criminal law. But it will be argued that negligence offences which require proof of harm are unhelpful when harm has not ensued. Instead, the paper will show that a more useful way to address the episode would be to use offences which aim to penalise deliberate breaches of safety regulations and do not require proof of any harm, whilst pointing out their limitations. In this respect, it will be shown that *mise en danger d’autrui* (deliberately putting someone in danger), the only offence in French criminal law which does not require proof of harm, has the potential to effectively ensure healthcare safety and deliver justice to harmed patients. The paper will also examine whether the use of corporate liability in this episode would achieve a greater degree of safety and could help in preventing further healthcare disasters. More particularly, it will explore whether prosecuting the PIP company would have been more helpful than prosecuting individual directors and more importantly, whether prosecuting the relevant regulators for failing to stop PIP directors’ breach would be an effective response to the episode.

⁷ French Agency for the Safety of Health Products.

⁸ ‘Jugement mis en délibéré à Marseille dans le procès PIP’, *Le Nouvel Observateur*, 17 May 2013 ; ‘France calls for Europe-wide control on prosthetics following PIP breast implant scare’, *The Telegraph*, 1 February 2012.

⁹ Sir Bruce Keogh, *Poly Implant Prothèse (PIP) breast implants: final report of the Expert Group*, Department of Health, June 2012, 1; Agence nationale de sécurité du médicament et des produits de santé, *PIP Breast Implants, Situation Update*, April 2013, 23; Scientific Committee on Emerging and Newly Identified Health Risks, *The Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants*, European Commission, 1 February 2012, 54; Z Kmietowicz, ‘PIP implants don’t pose risk to health, expert group concludes’, *British Medical Journal*, 18 June 2012.

¹⁰ Scientific Committee on Emerging and Newly Identified Health Risks, above n9 at 55.

¹¹ See above n3.

2. Criminal proceedings in the PIP implants scandal

Medical devices in the European Union are regulated by the Medical Devices Directive¹² which was transposed in France in several provisions of the French public health code¹³ and in England in the Medical Devices Regulations 2002.¹⁴ National institutions in charge of making sure that the relevant regulations are complied with are Agence nationale de sécurité du médicament et des produits de santé¹⁵ (ANSM-formerly Afssaps) in France and the Medicines and Healthcare Products Regulatory Agency (MHRA) in England. Under the French Code de Santé Publique, a person or institution can be liable to pay financial penalties if breaching the Medical Devices Directive. In England, the MHRA can prosecute a person in breach of the regulations for an offence under section 12 of the Consumer Protection Act 1987 (CPA) and punish up to 6 months imprisonment. It will be shown in the next part that the French offence of *tromperie* is very similar to offences against the safety regulations at section 12 CPA.

From 2001 to 2010, PIP, a French private company created in 1991 and directed by Jean-Claude Mas, manufactured and supplied breast implants made with industrial grade silicone to thousands of patients.¹⁶ Since 2007, Afssaps had been warned that there was an unusual rate of rupture in PIP implants.¹⁷ In March 2010 Afssaps removed all PIP implants from the market and a few months later, preliminary criminal investigations started in Marseille on the grounds of both fraud offences and negligence offences. Namely the offences used were *tromperie aggravée* (aggravated deception) and *mise en danger de la vie d'autrui* (putting someone in danger).¹⁸ In 2011 criminal investigations started in Marseille for *blessures involontaires* (involuntary wounding) and *homicide involontaire* (involuntary homicide) following the complaint of the mother of a patient with PIP implants who had died of cancer in 2010. In January 2012 Mas was prosecuted for *blessures involontaires* along with Claude Couty (former president of PIP directory) and they are *témoins assistés*¹⁹ for the charge of *homicide involontaire* (because there is no evidence as yet of a link between rupture of the implants and breast cancer).²⁰

¹² Directive 93/42/EEC.

¹³ Articles L5211-1 to L5214-2 Code de la santé publique.

¹⁴ The Medical Devices Regulations 2002.

¹⁵ French Medicine and Health Products Safety Agency.

¹⁶ Agence nationale de sécurité du médicament et des produits de santé, above n9 at 7.

¹⁷ A de Broqua, 'Prothèses PIP: première plainte contre l'Afssaps', *Le Figaro*, 1 February 2012.

¹⁸ 'Prothèses mammaires PIP: chronologie d'un scandale', *Le Monde*, 18 January 2012.

¹⁹ Under French criminal law 'any person implicated by a witness or against whom there is evidence making it seem probable that he could have participated, as the perpetrator or accomplice, in committing the offence of which the investigating judge is seized, may be heard as an assisted witness' (Article 113-2 Code de procédure pénale).

²⁰ A Jouan, M-A Lombard, 'PIP: les trois clés d'une enquête complexe', *Le Figaro*, 27 January 2012.

This section aims to analyse criminal proceedings involving PIP directors to find out whether in this context, the offence of *tromperie aggravée*, which has aspects of a consumer protection offence as found in section 12 of the CPA in England, could achieve the aims of deterrence, retribution, incapacitation and prevention, or at least some of these aims. It should be noted that the use of *tromperie* in this scandal has attracted criticisms from victims and victims' advocates who ask for 'justice' and retribution and for the use of offences against the person in addition. It has also been argued that 'compensatory and regulatory responses will not be able to contain any longer the vindictive desire of victims and the society at large which sees some of these conducts that result in healthcare scandals as 'industrial crimes''.²¹ However it will be shown that *tromperie* could be viewed as an acceptable and effective criminal response to the PIP scandal but the use of offences against the person which require proof of harm or death will be argued to be rather unsuitable in this context. Thus, offences which criminalise breaches of safety regulations could be better equipped to deal with company directors manufacturing defective medical devices and deliver justice to patients.

2.1 Criminal proceedings for *tromperie aggravée*

Despite criticisms expressed about *tromperie* when used as a response to healthcare scandals, it will be shown here that among the offences which can be used to deal with this particular episode, *tromperie* is at the moment the most suitable and effective to achieve the aims of deterrence, retribution, incapacitation and prevention. Because *tromperie* is not a 'traditional' fraud offence²² as we can find in England in the Theft Act 1968 and the Theft Act 1978, but contains elements of product liability and consumer protection found in section 12 CPA, this makes it particularly suitable to penalise PIP directors' conduct.

Proceedings and liability

On 10 December 2013 in the *Tribunal Correctionnel* of Marseille, Jean-Claude Mas was convicted of *fraude* and *tromperie sur les qualités substantielles* (deception on substantial qualities of the product) with the aggravated circumstance of *dangerosité pour la santé de l'homme ou de l'animal* (the use of which may be dangerous for human and animal health), an offence originally designed to criminalise fraud in the area of food retailing.²³ He was sentenced to four years in prison, fined 75000 Euros and banned from practising in the medical sector or from running a company.²⁴ Claude Couty, Hannelore Font (quality director), Loic Gossart (technical director) and Thierry

²¹ F Rousseau, 'Essai d'une reconfiguration des infractions pénales contre les personnes à l'aune des 'scandales sanitaires'', *Droit pénal* no 5, Mai 2013, Etude 11.

²² M Kazarian, above n5 at 125.

²³ See L213-1, L213-2 Code de la consommation; M Kazarian, above n5 at 159.

²⁴ 'Prothèses PIP: Jean-Claude Mas condamné à quatre ans de prison', *Libération*, 10 December 2013

Brinon (products director) were charged with being accessories to *fraude* and *tromperie aggravée*. Couty was sentenced to three years in prison with two years suspended, Font and Gossart were sentenced to two years with one suspended and Brinon was sentenced to 18 months suspended.²⁵ The evidence shows that Jean-Claude Mas and his colleagues within PIP had been knowingly using a low grade industrial silicone in breast implants. For ten years, they were aware of the fact that they were using unauthorised silicone and that it could potentially be harmful to patients. Jean-Claude Mas, when interrogated by police officers, claimed that he knew the silicone filler used by the company was unauthorised by the relevant regulations but he knowingly used it because 'it was cheaper and of far better quality'.²⁶ Couty declared that 'everyone knew the gel was not dangerous but there was a regulatory gap'.²⁷ Other defendants argued that they were not aware of the risks using the silicone filler and that blowing the whistle could jeopardize people's careers in the company.²⁸ Before each control, PIP employees used to hide raw material and accounting documents. One employee stated that after each TUV audit, PIP staff would have drinks to celebrate.²⁹ It has even been estimated that the use of the unauthorised gel by PIP helped the company save €1 million per year.³⁰ PIP directors thus demonstrated a clear intention to deceive patients. Prosecutors and judges considered that there was undeniable evidence to convict PIP directors for deceiving patients on the qualities of breast implants and that the implants could be harmful (they could cause leakage and risk of injury during removal).

It seems that an offence criminalising deception is therefore suitable to punish PIP directors on those grounds. *Tromperie aggravée* set out in Article L213-1³¹ of the French consumer code is more than just a fraud offence as it is a hybrid offence. It has aspects of both a fraud offence and a product liability/consumer protection offence, similar to offences under section 12 CPA in England. It could therefore be regarded as particularly useful when punishing company directors who have knowingly manufactured and provided defective and potentially dangerous medical devices to patients. The French consumer code provides, since 2014, that the maximum punishment for *tromperie* is two years imprisonment and a fine of €300,000, and is punishable by 5 years imprisonment and a fine of €600,000 when aggravated, whereas the CPA provides that the

²⁵ Ibid.

²⁶ 'Après Jean-Claude Mas, une deuxième mise en examen chez PIP', *Le Nouvel Observateur* 27 January 2012.

²⁷ 'Procès PIP: Claude Couty n'est pas un monstre calculateur', *VarMatin* 16 May 2013.

²⁸ 'Procès PIP à Marseille: la parole à l'accusation', *Le Nouvel Observateur* 14 May 2013.

²⁹ L Leroux, 'Procès hors norme du scandale des prothèses PIP', *Le Monde*, 17 April 2013.

³⁰ Ibid.

³¹ Article L213-1 Code de la consommation was revised in March 2014 by Loi no 2014-344 which increased the penalties provided in the article. PIP directors were convicted under the old article L213-1 which provided that 'anyone, whether or not they are party to the contract, who may have deceived or attempted to deceive the contractor, by any procedural means whatsoever, even if this is through the intermediary of a third party, shall be punished by two years imprisonment and a €37,500 fine: (1) either in respect of the nature, species, origin, material qualities, composition or content in terms of useful principles of any merchandise; [...] (3) or on the fitness for use, the risks inherent in use of the product, the checks carried out, the operating procedures or precautions to be taken'; The penalties were doubled if the offence was aggravated.

maximum penalty for an offence under section 12 is only 6 months imprisonment.³² *Tromperie aggravée* could then arguably be an offence which satisfies the aims of deterrence, retribution and incapacitation. It should be noted that *homicide involontaire*, even when aggravated, has a maximum penalty of 5 years imprisonment and a fine of €75,000. If the aim is to deter healthcare company directors from deceiving regulators and patients by using large fines and prison sentences, then *tromperie aggravée* could be said to be more effective than *homicide involontaire*.

Limitations

Nevertheless, the French offence of *tromperie* has limitations and has been heavily criticised in previous healthcare scandals. The main grounds for the criticisms were that *tromperie* is what the literature has called a *délit d'épicier* ('grocer offence'), not appropriate to criminalise malpractice in the healthcare context³³, and overall not sufficient to represent the tragic nature of healthcare disasters. The aggravating circumstance was also criticised because it did not specially aim to protect humans but also animals. Victims in the blood scandal felt very offended by the use of this offence for these two reasons. It was therefore claimed that *tromperie* was limited in achieving the aims of retribution and justice. Interestingly, even though some victims have expressed dissatisfaction at the end of the proceedings for *tromperie*, the level of outrage found in the blood scandal was not recorded in the PIP scandal and some victims even declared that this first decision was an important one as it was the first step towards justice.³⁴

It was nonetheless argued that *tromperie* was chosen by prosecutors as a quick criminal response to the scandal.³⁵ Some of the victims' advocates also asked for the use of offences which are appropriate to represent the level of seriousness of PIP directors' conduct. Victims are thus asking to at least be recognised by the criminal justice system as harmed patients, rather than mere consumers. The choice of offence may thus affect the degree of justice delivered to victims, even at least symbolically, and using an offence designed to punish conduct which affects the bodily integrity of individuals could arguably deliver appropriate justice to patients.

It is also important to remember that even though there is no evidence so far as to whether the substance used could cause damage to health, PIP implants have a higher rate of rupture than other breast implants and they have caused discomfort and anxiety to patients. During PIP directors' trial for *tromperie*, prosecutor Jacques Dallest even recognised that what patients were facing was '...pain and suffering, disease and fear of disease, death and fear of death'.³⁶ He thus

³² L213-1, L213-2, L213-3 Code de la consommation.

³³ M Kazarian, above n5 at 159.

³⁴ 'Prothèses PIP: Premières condamnations', *Euronews*, 10 December 2013.

³⁵ L Leroux, above n28.

³⁶ P Robert-Diard, 'Au procès des prothèses mammaires PIP, la défense a plaidé contre "le maléfice du doute"', *Le Monde*, 18 May 2013.

asked the court that a *prejudice d'anxiété* (damage for anxiety) be admitted.³⁷ Consequently even though it cannot at present be proven that the implants could cause cancer and death, they are still a potential threat to health as a result of the fear, anxiety and extreme discomfort experienced by patients, who should be recognised as such.

The evidence shows that PIP directors not only deceived regulators and patients but also deliberately put patients at risk of harm. Jean-Claude Mas and his colleagues knew that the substance used for the implants was not authorised by relevant regulations and therefore could potentially cause harm to thousands of patients but they voluntarily used this particular substance in breast implants. Therefore, it will be argued in the next section that PIP directors demonstrated deliberate conduct and it is important to find an appropriate offence to criminalise PIP directors on the grounds of deliberate endangering.

2.2 Criminalising PIP directors' deliberate conduct

In the second set of proceedings arising out of the PIP scandal, two PIP directors are being prosecuted for *blessures involontaires* (involuntary wounding). This section will evaluate the usefulness of *blessures involontaires* in this episode and see whether more appropriate offences could be found to penalise PIP directors' deliberate conduct. It is argued that errors, being unintentional and which 'do not involve moral culpability', are not easily deterred.³⁸ Violations on the other hand, demonstrate a level of deliberate departure from 'those practices appreciated by the individual as being required by regulation, or necessary or advisable to achieve an appropriate objective while maintaining the safety of people and equipment and the ongoing operation of a device or system'.³⁹ These can be more easily deterred because they involve an element of choice.⁴⁰ It is argued here that PIP directors committed a 'violation' by breaching safety regulations on breast implants. PIP directors' conduct was more than just deception and was a case of deliberate endangering of patients. It seems therefore useful to use offences designed to penalise deliberate conduct in addition to fraud offences to make sure that victims are offered the appropriate level of justice and closure, and PIP directors are adequately punished.

It will be shown that in proceedings for *blessures involontaires*, it may be difficult to establish causation between conduct and harm since some victims have not yet shown any signs of harm. Additionally, there is at the moment no definite evidence to say that PIP implants can cause harm or death. Therefore, the section will propose that, rather than using offences which require proof of harm or death, like *blessures* or *homicide involontaires*, one solution would be to criminalise

³⁷ Ibid.

³⁸ A Merry, A McCall Smith, *Errors, Medicine and the Law* (Cambridge University Press 2001) 2.

³⁹ Ibid at 101.

⁴⁰ Ibid at 2.

deliberate endangering regardless of any harm caused. This could be achieved by the use of offences like the French *mise en danger d'autrui* or the English health and safety offences.

Proceedings for *blessures involontaires*

In the second set of criminal proceedings arising out of the PIP scandal, two directors, Mas and Couty are being prosecuted for *blessures involontaires* and are *témoins assistés*⁴¹ for the charge of *homicides involontaires* (involuntary homicide)⁴². The offence of *blessures involontaires* is set out in article 222-19 Code Pénal which states that

Causing a total incapacity to work in excess of three months to another person by clumsiness, rashness, inattention, negligence or breach of an obligation of safety or prudence imposed by statute or regulations [...] is punished by two years' imprisonment and a fine of €30,000.⁴³

When aggravated with *faute délibérée* (recklessness)⁴⁴, the penalty is increased to three years' imprisonment and to a fine of €45,000, which is less than the maximum penalty for *tromperie aggravée*.

Blessures and *homicide involontaires* are designed to punish negligent conduct which results in harm or death. They are among the criminal offences used in cases of healthcare malpractice and healthcare scandals in France.⁴⁵ Victims of the PIP scandal were unimpressed by the use of *tromperie* and asked for appropriate deterrence and retribution, and so prosecutors considered that the use of offences against the person would achieve those aims. The two offences seem at first to be attractive tools to criminalise conduct which results in harm or death as they only require proof of simple negligence when the causal link between conduct and harm is direct, unlike the English gross negligence manslaughter which always requires at least proof of gross negligence. This has been said to be one of the reasons explaining the wider use of the criminal law in healthcare malpractice in France.⁴⁶ However, in previous healthcare scandals, the use of the offences has proved difficult and did not meet victims' demands for retribution and deterrence⁴⁷ and it would be

⁴¹ See above n18.

⁴² Article 221-6 Code pénal provides that 'causing the death of another person by clumsiness, rashness, inattention, negligence or breach of an obligation of safety or prudence imposed by statute or regulations, in the circumstances and according to the distinctions laid down by article 121-3, constitutes manslaughter punished by three years' imprisonment and a fine of €45,000. In the event of a deliberate violation of an obligation of safety or prudence imposed by statute or regulations, the penalty is increased to five years' imprisonment and to a fine of €75,000'.

⁴³ Article 222-19 Code pénal.

⁴⁴ Article 222-19 Code pénal provides that 'in the event of a deliberate violation of an obligation of safety or prudence imposed by statute or regulation, the penalty incurred is increased to three years' imprisonment and to a fine of €45,000'. The concept of *faute délibérée* is the equivalent of the English concept of recklessness, which when used as a stand-alone offence, called *mise en danger délibérée*, is punishable by one year's imprisonment and a fine of €15,000; See Article 223-1 Code pénal.

⁴⁵ M Kazarian, above n5 at 42-43.

⁴⁶ Ibid.

⁴⁷ M Kazarian, above n5 at 161, 174.

reasonable to say that securing a conviction using *blessures involontaires* or *homicide involontaire* may prove troublesome in the PIP episode.

First, it will be difficult to prove that the accused have committed *blessures involontaires* because it will have to be proven that the implants actually caused injury to patients. Multiple expert reports would be required for each *partie civile*⁴⁸ to analyse explanted prostheses and determine their exact composition, and thus come to a conclusion on whether or not they could have caused injury to the victim's body. The number of *parties civiles* in these proceedings is 30000 and we could presume that the proceedings could take years to come to an end. Some victims have shown signs of minor harm and discomfort but will this be considered sufficient to satisfy the requirement of proving 'a total incapacity to work in excess of three months' as expressed in the French Code pénal?⁴⁹ Similarly, convicting PIP directors for *homicide involontaire* would be nearly impossible given that no link has been established between the implants and death.

If prosecutors and judges consider that there is enough evidence to say that the defendants have committed *blessures involontaires*, the penalty of two years imprisonment may not be considered sufficient by victims and instead, the aggravating circumstance of *faute délibérée* should also be used to meet victims' demands for retribution and deterrence.⁵⁰ The use of the aggravating circumstance in the proceedings may therefore be a decisive factor in ensuring that victims' demands for deterrence and retribution are met. However, practical difficulties attached to the use of the offence regarding causation may lead to extremely lengthy proceedings with a very unsatisfactory outcome for victims as there is no conclusive evidence at present that PIP implants can cause harm to patients. The solution could be to focus on the notion of 'risk' rather than actual harm or death, and prosecute healthcare providers for offences which criminalise the act of putting persons at risk without having to prove that any harm has ensued.

Criminalising deliberate endangering

The offence of *mise en danger d'autrui* found in Article 223-1 of the French penal code was designed to 'penalise conduct which demonstrates deliberate disregard to the social value of respect for life and bodily integrity'.⁵¹ It is the only offence in French criminal law which does not require proof of harm or death, which makes the offence particularly interesting and appropriate for cases like the PIP episode. Article 223-1 provides that:

⁴⁸ In France victims have the right to join civil claims for compensation to criminal complaints and thus obtain financial compensation for the harm caused, they are then called *parties civiles*.

⁴⁹ Article 222-19 Code pénal.

⁵⁰ Frédéric Joignot, 'Jugement au procès PIP. Les prothèses contenaient une énorme dose de cynisme gluant', *Le Monde*, 9 December 2013.

⁵¹ Jurisclasseur Pénal Code, Fasc. 20: Risques causés à autrui, mise à jour: 13 Mars 2015, 17.

The direct exposure of another person to an immediate risk of death or injury likely to cause mutilation or permanent disability by the manifestly deliberate violation of a specific obligation of safety or prudence imposed by any statute or regulation is punished by one year's imprisonment and a fine of €15,000.⁵²

This offence could therefore allow prosecuting directors of companies manufacturing medical devices who have deliberately put patients at risk but no harm has ensued at the time of the proceedings. Article 223-1 of the French penal code requires that there must have been a violation of a specific obligation of safety or prudence imposed by statute or regulation. In this affair, this should be easy to demonstrate as the use of unauthorised silicone filler in breast implants was in breach of regulatory provisions. It will also need to be proven that the victim was exposed to an immediate risk of death or injury. The Cour de Cassation (French Supreme Court) in this area considers that the risk of injury or death only needs to be potential and there is no need to prove that the defendant had knowledge of the risk when he committed the offence.⁵³ The requirement of potential risk of harm could be demonstrated by the fact that following the episode, patients had to have their implants removed and some of them showed signs of leakage, which could potentially cause further damage to their bodies. The main difficulty will be to prove that there was a direct causal link between violation and risk, but given the uncertainty of scientific evidence to say that PIP breast implants are completely safe, it seems that a certain risk could be established.

A proposal by the Sénat aimed to reform the offence by adding an alternative to the requirement of proving that there was a violation of a specific obligation of safety or prudence imposed by statute or regulation. The alternative would be to prove that there was gross negligence which exposed another to a serious risk which could not be ignored.⁵⁴ The aim was to broaden the scope of the offence and allow more effective criminalisation of grossly negligent behaviour which may cause risk to health, but which cannot be criminalised under the offences of *homicide* or *blessures involontaires*.⁵⁵ The proposal was rejected by Assemblée Nationale. Members of the Parliament feared that decision-makers would be prosecuted too easily under the offence, going against the aim of the reform made to negligence offences in 2000⁵⁶, which added the requirement of proving gross negligence when the causal link between conduct and injury was indirect.⁵⁷ The other reservation members of the Parliament expressed was that the offence provided for a very low

⁵² Article 223-1 Code Pénal.

⁵³ Jurisclasseur Pénal Code, above n49 at 16.

⁵⁴ Sénat, Proposition de loi relative à la délinquance d'imprudance et à une modification des dispositions de l'article 223-1 du code pénal instituant le délit de 'mise en danger délibérée de la personne d'autrui', 13 janvier 2011.

⁵⁵ F Rousseau, above n21.

⁵⁶ Loi n° 2000-647 du 10 juillet 2000, tendant à préciser la définition des délits non intentionnels (1) (JO 11 juill. 2000) 10484.

⁵⁷ F Rousseau, above n21.

prison penalty and might not be an appropriate response to healthcare or industrial scandals. However they appreciated that the offence required ambitious and close examination.⁵⁸ It could be argued that the extension of *mise en danger d'autrui* to gross negligent conduct may result in over-criminalisation as it may lead to criminal prosecutions even when there is no evidence of reckless or deliberate conduct. However the element of awareness of risk is to be welcomed. In this affair this would mean that PIP directors could not ignore the fact that PIP implants were potentially dangerous, knowing they were not authorised in the relevant regulations. The offence could however be revised to provide for a higher prison penalty, in the interest of ensuring proper retribution and deterrence.

Focusing on punishing conduct which deliberately breached safety regulations rather than conduct which caused actual harm or death could potentially be effective in ensuring appropriate deterrence in this area. Deterring company directors from breaching safety regulations could then have the effect of protecting patients from potential harm and preventing further healthcare disasters. Wells argues that the function of regulatory offences such as health and safety offences in England is to minimise risk directly, rather than focus on actual harm.⁵⁹ In England, the Health and Safety at Work Act 1974 (HSWA) contains a set of offences which could be used in the context of healthcare malpractice. In particular, section 33 of the Act contains a number of offences which could be useful in the prosecution of manufacturers of medical devices. It provides that 'it is an offence for a person [...] (c) to contravene any health and safety regulations [...] (k) to make a statement which he knows to be false or recklessly to make a statement which is false where the statement is made in purported compliance with a requirement to furnish any information imposed by or under any of the relevant statutory provisions'.⁶⁰ This provision seems to make possible the prosecution of an individual who has caused risk of harm or death in the health environment or recklessly deceived another on the qualities of a medical device, which in theory could apply to conduct like that demonstrated by PIP directors'. The maximum penalties for offences committed under section 33 (c) and (k) before 16 January 2009 are unlimited fines, while offences committed on or after 16 January 2009 are punishable by either an unlimited fine or 2 years imprisonment in the Crown Court, which is higher than the maximum penalty for *mise en danger d'autrui*.

The regulatory nature of offences contained in Article 223-1 Code Pénal in France, and the HSWA in England, which are specially designed to protect health and safety seem to be the most suitable form of criminal offences that may be used in cases like the PIP episode. They could effectively achieve some of the functions of the criminal law such as deterrence and prevention, and most importantly ensure healthcare safety. These offences, which focus on minimising risk, seem

⁵⁸ Ibid.

⁵⁹ C Wells, 'Corporate criminal liability: a ten year review', *Criminal Law Review*, 2014, 859.

⁶⁰ Section 33 HSWA.

therefore the most appropriate offences to ensure proper criminalisation of manufacturers of health devices who have deliberately breached safety regulations. However at the moment, the effectiveness of the penalty provided under Article 223-1 of the French penal code seems limited to ensure adequate deterrence, retribution and incapacitation, and *tromperie aggravée* remains the only offence capable of achieving those aims. The limitations are nevertheless that *tromperie aggravée* may not effectively ensure safety in the healthcare setting, as it is not specific to healthcare but relates more to product liability in general. It will then be worth looking at whether corporate liability in the PIP episode could better ensure a higher degree of safety in the area of medical devices.

3. Corporate liability

The PIP company went into administration in 2010 and was therefore never prosecuted for a corporate criminal offence.⁶¹ Although there were civil proceedings in France against TÜV, victims are asking for criminal accountability of the regulators, in particular Afssaps who, they say, failed in its duty to carry out effective inspections of the PIP company.⁶² The aim of this section is to see whether prosecuting the PIP company would have been a more effective option than individual liability to ensure appropriate deterrence and retribution, and whether prosecuting regulators would provide a higher degree of safety in medical devices and prevent further healthcare disasters.

Prosecuting the PIP company

As for individual negligence, French criminal law allows the criminalisation of corporate negligence which may or may not result in death. In France, corporations may be convicted of all criminal offences applicable to individuals and this includes *mise en danger d'autrui*.⁶³ The criminalisation of corporations is nonetheless not exclusive. In the same criminal proceedings, both corporations and individuals may be prosecuted and convicted of the same offences.⁶⁴ For a corporation to be criminalised, a criminal offence has to be committed by one of its bodies or representatives on its behalf.⁶⁵ Thus, if the corporation's representative has committed an offence, the corporation may be subject to criminal liability. As argued above, there is clear evidence that PIP director Jean-Claude Mas had committed a criminal offence, so the PIP company could have been subject to criminal liability under French criminal law.

⁶¹ 'Breast implants 'have no cancer link' says UK watchdog', *BBC News*, 21 December 2011.

⁶² Alette de Broqua, 'Prothèses PIP: première plainte contre l'Afssaps', *Le Figaro*, 1 February 2012 ; Alette de Broqua, 'PIP : l'organisme certificateur accusé de négligences', *Le Figaro*, 24 July 2012 ; 'Prothèses PIP : le certificateur TÜV va devoir indemniser les victimes', *Le Monde*, 14 November 2013.

⁶³ Article 121-2 Code Pénal; there are nonetheless certain limits regarding the criminalisation of *collectivités territoriales* (local authorities).

⁶⁴ *Ibid.*

⁶⁵ *Ibid.*

The same questions as for the criminal liability of individual employees and directors of PIP arise as to what offence should be used to criminalise PIP and whether corporate liability would have achieved a greater degree of healthcare safety and deterred company directors from breaching safety regulations. The same issues related to the use of *homicide involontaire* or *blessures involontaires* would have arisen if they had been used as corporate offences against the PIP company. Once again it seems that the most appropriate offence which could have been used here is *mise en danger d'autrui* as no harm would have been required to be proven and this would have solved problems linked to proving causation and could have ensured recognition of the level of moral culpability on the part of PIP. Corporate liability could have been particularly useful here because there would have been no need to prove individual failure as proving that the company as a whole deliberately put patients at risk of harm would have been sufficient. French criminal offences are arguably easy to use against corporations in cases of healthcare malpractice.⁶⁶ On the other hand, in England, the Corporate Manslaughter and Corporate Homicide Act 2007 (CMCH 2007) is inadequate and fails to ensure proper and coherent criminalisation of healthcare institutions and companies.⁶⁷ It is particularly ineffective when criminalising conduct which only results in injury, which French offences can address. Again, offences under the HSWA⁶⁸ seem to offer more appropriate criminalisation of corporate conduct for at least two reasons: the Act specifically targets healthcare safety and it criminalises conduct resulting in injury, and not only death. Quick notes that HSWA focuses 'squarely on safety, and particularly the contribution of flawed systems'.⁶⁹ This would be particularly useful when the aim is to ensure healthcare safety rather than mere punishment of corporations.

It is alternatively argued that 'the threat of criminal sanctions alone has the power to compel corporate decision-makers to abandon their exclusively economic calculus of thought and action and, for the first time, to begin to base their behaviour on a serious consideration of the human consequences of their actions'.⁷⁰ Therefore in theory, managers in commercial corporations weigh the costs and benefits of the consequences of a decision so they might be deterred by the prospect of corporate punishment, and this might in turn ensure safety in companies manufacturing medical devices.⁷¹ But as the PIP episode has shown, the threat of corporate punishment contained in the French penal code does not seem to have deterred PIP directors from manufacturing potentially dangerous breast implants.

⁶⁶ M Kazarian, above n5 at 48.

⁶⁷ C Wells, 'Medical Manslaughter: Organisational Liability', in D Griffiths, A Sanders (eds) *Medicine, Crime and Society*, Cambridge University Press 2013, 192; P Gooderham, 'No-one fully responsible: a 'collusion of anonymity' protecting health care bodies from manslaughter charges?' (2011) *Clinical Ethics* 68.

⁶⁸ Section 37 HSWA.

⁶⁹ O Quick, 'Patient safety and the problem and potential of law' (2012) *Journal of Professional Negligence* 97.

⁷⁰ R Engineer, 'Punishing Corporate Negligence, Industrial Disasters and Criminal Law' (1989) 24(14) *Economic and Political Weekly* 711.

⁷¹ R Engineer, above n68 at 713.

Therefore, it is safe to say that at least in this episode, the effect of corporate punishment against PIP would have been limited. Merry and McCall Smith noted that ‘if the objective is to deter unsafe practices, it is very important to include within the scope of that deterrence those who actually have the authority to change those practices’.⁷² It was thus argued in relation to healthcare malpractice in general, that the focus should be put on individual directors who had the power to make decisions and whose decisions caused thousands of victims to be in danger⁷³ rather than prosecuting the institution or company. Consequently, in cases where company directors voluntarily breached safety regulations and deliberately put patients at risk, the criminalisation should focus on individual directors rather than the company as a whole, in the interest of ensuring appropriate punishment, and patient safety. The question remains whether prosecuting healthcare regulators would also help in addressing the issue of safety, and whether in the PIP episode, regulators should be prosecuted at all.

Prosecuting regulating bodies

As argued earlier, only recklessness or deliberate conduct should attract criminal liability in the context of healthcare malpractice. The aim of this subsection is to see whether the relevant regulators committed a criminal offence and whether prosecuting these institutions would achieve a greater degree of safety in medical devices. Victims of the episode are asking for criminal prosecutions of the regulators, but as will be shown, there is limited evidence to say that the regulators committed a criminal offence in this episode.

The regulatory system which should have prevented the PIP scandal from happening was said to be a ‘smoke-screen for faulty and dangerous devices that placed patients and surgeons at risk’.⁷⁴ The assessment of medical devices in the European Union (EU) is performed by Notified Bodies (NBs). Their role is to ‘determine the safety and effectiveness of a device and to issue a certificate of conformity’.⁷⁵ TUV Rheinland was commissioned by PIP as NB to conduct assessment procedures in accordance with the Medical Devices Directive which provides that ‘the [NB] must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system’.⁷⁶ It also states that ‘in addition, the [NB] may pay unannounced visits to the manufacturer’.⁷⁷

⁷² A Merry, A McCall Smith, above n37 at 214.

⁷³ M Kazarian, above n5 at 247.

⁷⁴ R Horton, ‘Offline: The scandal of device regulation in the UK’, *The Lancet* Vol 379, January 14, 2012, 106.

⁷⁵ Afssaps/DGS, *Etat des lieux des contrôles opérés par les autorités sanitaires sur la société Poly Implant Prothèse*, 1 February 2012, 8; R Horton, ‘The scandal of device regulation in the UK’, *The Lancet*, vol 379, January 21, 2012, 204.

⁷⁶ Medical Devices Directive (93/42/EEC) Annex II, 5.3.

⁷⁷ *Ibid* at 5.4.

It is said that 'once the [NB]'s initial job is done and a product is on the market, it's up to national regulators to keep a look out for problems and ensure the [NB] is keeping tabs'.⁷⁸ In 2000 the Food and Drug Administration (FDA) inspection in the United States published a letter on their website to inform that they had found that some products manufactured by PIP were 'adulterated'.⁷⁹ Afssaps' director of evaluation for medical devices Jean-Claude Ghislain claimed that Afssaps had not been warned in a 'proactive' way and he argued that they could not 'check at every moment other countries' health authorities' websites'.⁸⁰ But US regulators claimed that French regulators could have been more vigilant.⁸¹ TUV spokesman argued that TUV was only in charge of auditing PIP's manufacturing processes and there was an assumption that 'a firm is responsible and liable, and would have too much to lose to cut corners'.⁸² The PIP episode proved otherwise. In the UK, concerns over PIP implants were first noted in 2008, two years after surgeons had publicly reported problems with the implants and stated that 'the reliability of PIP implants must be questioned'.⁸³ It has been argued that 'the MHRA failed to do the job the public expects of it - to protect it from harm'.⁸⁴

The question remains whether TUV, Afssaps and the MHRA should be considered criminally culpable. Afssaps and the MHRA could be blamed for ignoring warnings on the risks that could potentially be caused by PIP implants, or for ignoring the precautionary principle⁸⁵. TUV could be blamed for not conducting unannounced visits to PIP. But it would seem unreasonable to say that these institutions had a reckless state of mind and thus should be punished for failing to uncover what was going on in the PIP company. It was found that between 2002 and 2008, apart from regular controls by TUV, of which annual reports were not sent to Afssaps, the follow-up of the PIP company was conducted through surveillance data which did not provide any significant warning on a serious risk to health compared to other providers.⁸⁶ But from 2008, warnings increased and this led to the Afssaps inspection in March 2010 where the fraud was discovered.⁸⁷ Similarly, it was concluded that 'there is no evidence in relation to PIP implants that the MHRA or the wider Department of Health significantly failed to do their job'.⁸⁸ In-depth investigations into this matter should be conducted to determine whether or not TUV, Afssaps or the MHRA had the level of

⁷⁸ K Kelland, 'Insight: In PIP implant scandal, a ragged safety net exposed', *Reuters*, 3 February 2012.

⁷⁹ *Ibid.*

⁸⁰ *Ibid.*

⁸¹ *Ibid.*

⁸² *Ibid.*

⁸³ R Horton, above n74.

⁸⁴ *Ibid.*

⁸⁵ The precautionary principle provides that precautionary measures should be taken when a potential risk to health is known; see E Hergon et al., 'Risk Management in Transfusion After the HIV Blood Contamination Crisis in France: The Impact of the Precautionary Principle' (2005) 19(4) *Transfusion Medicine Reviews* 273.

⁸⁶ Afssaps/DGS, above n73 at 160.

⁸⁷ *Ibid.* at 161.

⁸⁸ Department of Health, *Poly Implant Prothèse (PIP) silicone breast implants, Review of the actions of the Medicines and healthcare products Regulatory Agency (MHRA) and Department of Health*, May 2012, 13.

culpability required to deserve criminal punishment, which goes beyond the scope of this paper. So far, the evidence suggests that regulators only showed mere negligence and thus should not be held criminally liable. Consequently, using the criminal law against regulators when they were merely negligent would seem inappropriate and unhelpful in this episode. Rather, alternatives should be sought to make sure that medical devices are safe, and to prevent similar healthcare disasters.⁸⁹

The first step towards making medical devices and products safe is to determine what can be learnt from the PIP episode. The scandal highlighted problems in control systems in the regulation of health products and this led to several inquiries being conducted in France, England and at the European level. These inquiries aimed to evaluate the harm potentially caused by PIP implants and propose solutions to ensure compliance with regulation in the area of medicine and health products.⁹⁰ Reports and reforms have focused on crucial issues such as improving transparency and controls, and encouraging regulatory compliance.

In February 2012, a report by Afssaps and Direction générale de la Santé (DGS)⁹¹ provided with a chronology of actions taken by Afssaps regarding PIP, an analysis of health risks generated by PIP implants and a list of recommendations to improve regulatory controls in the area of medical devices.⁹² Among the recommendations, the report proposed to increase the number of controls and unannounced visits to medical devices companies.⁹³ It also suggested that all warnings, wherever they come from, should be taken into account.⁹⁴ The report finally advised that the Medical Devices Directive be revised to make it more efficient, arguing that NBs should conduct more unannounced visits and that there should be sanctions against NBs when deficiencies are highlighted by controls conducted by member states' authorities.⁹⁵

At the time of writing, the European Commission is in the process of enacting an EU regulation which will reform the current system based on directives. The regulation will be directly applicable and thus ensure consistency in all Member States. Among the Commission's proposals, NBs' powers will be clarified and enhanced, and the Commission has stated the need to undertake unannounced visits by NBs.⁹⁶ Also, the proposals state the need for greater transparency and improved traceability of medical devices. The Commission's proposal is to be welcomed, especially

⁸⁹ M Kazarian, above n5 at 254.

⁹⁰ Sir Bruce Keogh, above n9; Scientific Committee on Emerging and Newly Identified Health Risks, above n9; M Lochouarn, 'France launches new drug regulatory agency', *The Lancet* Volume 379, Issue 9832, 9 June 2012, 2136; Department of Health, above n88.

⁹¹ French Direction General of Health.

⁹² Afssaps/DGS, above n75.

⁹³ *ibid* at 162.

⁹⁴ *ibid* at 163.

⁹⁵ *ibid* at 165.

⁹⁶ European Commission, Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, p 8

with regards to the powers of NBs, although it seems that the reference to the power to undertake unannounced visits may not make a significant difference in practice as the existing regulations already provided for unannounced visits to be undertaken by NBs.

In the United Kingdom, a report by Lord Howe also aimed to determine ‘whether the actions of the UK regulator, the MHRA, and the UK Government, could have reasonably prevented or alleviated this considerable distress, or indeed uncovered the fraud earlier’.⁹⁷ It proposed that ‘we must ensure that there are effective deterrents to undertaking this kind of fraud, and that the regulatory bodies are well-equipped as possible to investigate any concerns they have, to ensure such fraud is detected and punished’.⁹⁸ It seems that if put into practice, Lord Howe’s proposals could effectively address issues arising out of the PIP episode. It would also be worth looking into what role the criminal law could play as a means to ensure regulatory compliance.

Another very important change was made to Afssaps, which has now become ANSM⁹⁹. The reform focused very much on improving transparency and it was said that ‘the major change is definitely that ANSM will permit to conjugate a constant re-examination of benefits and risks of using medicines, medical devices, and other human health products throughout all their life cycle, with an early and rapid access to innovative medicines’.¹⁰⁰ The director general of ANSM stated that ‘transparency is also newly enlarged with wide access [for the] public to the entire process of decision [making], through most documents, videotapes of working commissions, [and] public hearings’.¹⁰¹

These inquiries and reports attempt to address issues arising out of the PIP episode and relating to the safety of medical devices. It remains to be seen whether these proposals and reforms can effectively make the system safer. Editor of the Lancet Richard Horton stated that until the system is improved, ‘we’re sitting on a time bomb which could explode at any moment’.¹⁰² Regulators and health authorities have therefore to find quick and effective solutions on how to improve medical devices safety as the criminal law can only achieve so much for healthcare safety.

4. Conclusion

This paper aimed to analyse the use of the criminal in the PIP episode. It first examined criminal proceedings for *tromperie aggravée* involving PIP directors and showed that *tromperie aggravée*, with its unique features, was a suitable offence to penalise PIP directors’ fraudulent conduct in

⁹⁷ Department of Health, above n88 at 11.

⁹⁸ Ibid at 13.

⁹⁹ See above n15.

¹⁰⁰ M Lochouarn, above n90 at, 2136.

¹⁰¹ Ibid.

¹⁰² K Kelland, ‘Insight: In PIP implant scandal, a ragged safety net exposed’, *Reuters*, 3 February 2012.

providing defective breast implants to patients. The offence seemed to be capable of addressing the aims of deterrence, retribution and incapacitation, however, it was limited in punishing PIP directors' deliberate endangering of patients.

The paper then demonstrated that the use of classic negligence offences, particularly *blessures involontaires*, which has been used to prosecute PIP directors in a second set of proceedings, may not lead to a satisfactory outcome for either victims or the public in general. The offence requires proof of injury and a significant number of PIP victims have not shown signs of any bodily harm. The paper thus showed that a more useful way to tackle PIP directors' reckless conduct would be to use offences which do not require proof of harm and which aim to punish breaches of safety regulations. In this respect, a lot can be learnt from the French offence of *mise en danger d'autrui* and English health and safety offences. However, law-makers should look at whether penalties attached to these offences could be increased to make them more effective in the punishment of company directors who have deliberately breached safety regulations, and to satisfy victims' demands for justice.

Finally, the paper explored whether corporate liability could be a more effective option than individual liability to ensure safety in the area of medical devices. Arguably, prosecuting the PIP company would have had only a limited effect in deterring deliberate breaches of safety regulations, and focusing on individual directors seems a more effective response to this type of healthcare scandals. After examining failings by regulatory institutions to see whether they should be held criminally liable, it was found that at the moment there is not enough evidence to hold regulators criminally liable but alternatives to the criminal law would be more useful to address regulatory issues in the area of medical devices. Current reforms seem to be targeting key issues regarding medical devices and safety regulations, but it remains to be seen whether in practice these reforms will effectively improve safety.

ⁱ I am grateful to Margot Brazier, Alex Mullock and Daniel Bedford for helpful comments and suggestions on an earlier draft of this paper.