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The third edition of the *Journal of Rights and Justice* has maintained the standards set by the two previous volumes, showcasing a diversity of legal analysis and subject matter. On this occasion we have two substantial and conventional academic articles, and an exciting new development in the form of an in-depth interview with a leading figure in the juridical world.

Our opening article is by Muhammad Tanvir Hashem Munim, and deals with the International Criminal Court, the concept of universal jurisdiction and the appropriate application of this principle within the contemporary legal sphere. Maria Merkow then addresses the problem of how law regulates the drug development process, up to the point of market authorisation, and teases out the relationship between the existing legislation and the various expressions of pharmaceuticalisation. Finally, Linda Mururu presents and interview with Linda Weil-Curiel, French advocate and women's rights activist. Her legal work and tireless social activism has prevented countless young girls in France from suffering female sexual mutilation, and the lifelong consequences of such harm.

At first glance, these topics may seem poles apart, and indeed the spread of expertise and commentary is extremely positive. However, it will also be apparent to readers that all of the articles addresses legal issues arises from the global nature of human society in the 21st century, and the challenges which both national and transnational systems of regulation have in balancing competing needs and interests, as well as fundamental rights and freedom in the modern era, alongside the pragmatic considerations of enforcement. Read holistically, this volume provides a fascinating range of insights and reflections.

As always, the journal is dependent upon the hard work, professionalism and dedication of the editorial team. My heartfelt thanks go to Dr. Ryan Cushley-Spendiff for his energy and attention to detail as Deputy Editor, and for the invaluable administrative support of Kerri Gilbert. I am grateful as always to Prof Tom Lewis (Director of the Centre for Rights and Justice) and Prof Jonathan Doak (Associate Dean for Research, Nottingham Law School) for their wise advice and encouragement. Finally, although they must, for obvious reasons remain anonymous, I am hugely appreciative of the colleagues who have given their time and skill to undertake peer reviews, as without them, the journal could not exist in its present form.

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UNIVERSAL JURISDICTION AND THE INTERNATIONAL CRIMINAL COURT (ICC): A PRAGMATIC AND HOLISTIC APPROACH TO THE CONSIDERATION AND APPLICATION OF UNIVERSAL JURISDICTION BY THE ICC

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Abstract

The article portrays the fact that the International Criminal Court (ICC) exercises universal jurisdiction albeit quasi in nature. The proactive interpretation of the Article 12 of the Rome Statute by the ICC, the spirit of the Rome Statute, the decisions of other international tribunals, and the recognized doctrines of international law provide firm support for the ICC to exercise true universal jurisdiction. The article has taken a holistic approach towards the existing literatures relevant to the Universal Jurisdiction of ICC with a priority to case laws of ICC. Decisions of international criminal tribunals including the ICC have been critically considered to find the status of Universal Jurisdiction in International Criminal Law Jurisprudence. The decisions of ICC rendered at different stage in the situation in Bangladesh/Myanmar, Afghanistan and Palestine are discussed at length as they involve countries not party to the Rome Statute i.e. Myanmar, the US, and Israel, and thus the issue of exercising Universal Jurisdiction appeared either obliquely or in disguise in these situations. The article is an attempt to add value to the present jurisdictional practice exercised by the ICC. It aims to provide support to further the jurisdictional reach of the ICC so it can become a true international criminal court with true universal jurisdiction to truly align with the purpose of the Rome Statute – putting an end to impunity for the most serious crimes.

INTRODUCTION

Universal jurisdiction of the International Criminal Court (ICC) in its simplest form means that the ICC can exercise its jurisdiction over a crime, irrespective of it having a territorial, personal or other connection to the crime.[1] This is known as true or pure universal jurisdiction.[2] In this work the terms 'true universal jurisdiction' and 'universal jurisdiction' are used interchangeably. Among different jurisdictions (e.g. territorial, temporal, personal, subject matter *etc.*) the universal jurisdiction of the ICC can be a vital tool in the present world of globalisation to bring the nations together for building a better world, given that universal jurisdiction can be a catalyst to bring the ideal of universal justice closer to reality.[3] Unfortunately, the ICC has not been given the power to prosecute under true universal jurisdiction, but it exercises quasi-universal jurisdiction in some respects.[4] Nevertheless, in this work we will discuss how close the jurisdiction of the ICC comes to being universal. In doing so, we will closely look into the extent to which universal jurisdiction has been considered and applied by the ICC.

The history of the ICC during its drafting stage bears testimony to the fact that there has been a compromise by the drafters of the Rome Statute[5] not to bestow universal jurisdiction to the ICC. Some States were fierce opponents of the universal jurisdiction[6] and some thought that universal jurisdiction was far too ambitious as States rarely exercise the same and thus would be met with opposition from States resulting in refusal to ratify the Rome Statute.[7] Some States even went further in arguing the legality of ICC as a court that can exercise universal jurisdiction; the US argued that 'there was no rationale in law' for such a court.[8] These debates culminated in Article 12 of the Rome Statute that reflects the compromise with universal jurisdiction,[9] limited the jurisdiction from the aspirational standards of universal jurisdiction

and states that the ICC has jurisdiction over crimes committed on the territory of state parties and over nationals of state parties:

> 'Article 12(2): ……..the Court may exercise its jurisdiction if one or more of the following States are parties to this Statute or have accepted the jurisdiction of the Court in accordance with paragraph 3: (a) The State on the territory of which the conduct in question occurred or, if the crime was committed on board a vessel or aircraft, the State of registration of that vessel or aircraft; (b) The State of which the person accused of the crime is a national.'

However, as the seed of universal jurisdiction was there during the inception of the ICC, if not in the statute but in the talks,[10] it can be hoped that calculated incremental steps towards achieving the same might someday award universal jurisdiction to the ICC. As universal jurisdiction was strongly argued and debated at length during the pre-drafting and drafting stages,[11] as well as during the Rome Conference,[12] an incremental approach to modify the current Article 12 may eventually be accepted by the opponents if their concerns can be addressed properly. But this cannot be achieved overnight. Further, the existing jurisdictions of ICC and universal jurisdiction itself have to be considered precisely to form insights and argue solution(s). A pragmatic approach is needed that will judge the possibility of exercising universal jurisdiction by the ICC with existing and possible impediments. Further, a utilitarian approach as to whether the same 'should' be exercised by the ICC may complement the pragmatic approach.[13] Overall, a holistic approach that takes care of all the possible aspects of bestowing universal jurisdiction to the ICC will eventually pave the road towards a

workable suggestion in bestowing universal jurisdiction on the ICC. However, the author suggests that the ICC should have true universal jurisdiction.

ICC AND JURISDICTION

Jurisdiction has been an issue ever since the inception of the ICC and continues to be until the present day. Given the ICC's holistic nature compared to other prominent international criminal tribunals e.g. the Nuremberg Tribunal, International Criminal Tribunal for Former Rwanda (ICTR) *etc.*, as the ICC was not setup for a specific conflict or event, the ICC faces frequent challenges in determining its jurisdiction to try a particular case.[14] The Nuremberg Tribunal had personal jurisdiction to try and punish persons acting in the interests of the European Axis Countries, who committed one of the crimes amenable to the tribunal;[15] the ICTR had both territorial and personal jurisdictions to try Rwandan nationals for committing crimes in neighbouring countries.[16] But it is member States' wilful submission to the jurisdiction of ICC, as joining the Rome Statute is a sovereign and voluntary decision for each state to make,[17] that draws the main distinction between the ICC and the aforesaid courts in the context of jurisdiction. Further, universal jurisdiction is the widest and most ambitious form of jurisdiction for the ICC that has already been met with serious opposition from States like the United States ever since the idea of a true International Criminal Court started to take shape through the drafting of Rome Statute. As such, an introduction to the applicable types of jurisdictions of the ICC is necessary as they will be referred to elsewhere in this work.

As such there are subject matter, temporal, territorial and personal jurisdictions of the ICC.[18] If an alleged crime falls within the categories of the crimes the ICC can prosecute then the ICC has subject matter jurisdiction (*ratione materiae*) to try the offender of the crime. The

crimes are genocide,[19] crimes against humanity,[20] war crimes,[21] and aggression.[22] Temporal jurisdiction (*rationie temporis*) means the ICC can only exercise jurisdiction over crimes that are committed after the entry into force of the Statute i.e. after 1 July 2002.[23] Territorial jurisdiction (*rationie loci*) refers to the fact that the ICC can only exercise jurisdiction over crimes that are committed on the territory of State parties, irrespective of the offender's nationality.[24] Personal Jurisdiction (*rationae personae*) grants the ICC the jurisdiction to try the nationals of a State party accused of a crime.[25] It is worth noting that if a State temporarily accepts the jurisdiction of the ICC on an *ad hoc* basis then the ICC has territorial jurisdiction over the crimes committed on the territory of that State;[26] the same principle applies with regard to personal jurisdiction over nationals of non-State parties if that State accept ICC's jurisdiction on an *ad hoc* basis.[27] Further, the ICC can exercise territorial and personal jurisdiction over any 'situation in which one or more of such crimes appears to have been committed is referred to the Prosecutor by the Security Council acting under Chapter VII of the Charter of the United Nations.'[28]

UNIVERSAL JURISDICTION AND THE ICC

Basis For Universal Jurisdiction.

Universal jurisdiction is the remotest form of extraterritorial jurisdiction.[29] Extra territorial jurisdiction in this context means a state exercising jurisdiction over certain offences committed outside the territory of that state.[30] There are extraterritorial jurisdictions that retain a connection to the territory thereby engaging a link to the state, but universal jurisdiction gives a prosecuting state the right to exercise jurisdiction over extraterritorial crimes committed by foreign nationals even against foreign nationals.[31] The main basis of exercising universal

jurisdiction as propagated by international lawyers like Rosalyn C. Higgins and Malcolm N. Shaw is that the prosecuting state has a legal right to exercise jurisdiction over certain offences as those were committed against the international community as a whole[32] and hence are offensive to the international community as a whole.[33]

The aforesaid basis calls for a close look into the two interrelated maxims that operate within the dynamics of universal jurisdiction in the context of international law. The maxims are *jus cogens* and *obligatio erga omnes. Jus cogens* means compelling law or peremptory norm which is a fundamental principle of international law that is accepted by the international community of states as a norm from which no derogation is permitted.[34] The authority of this peremptory norm is so firm that even treaty or customary rules will become void if they run contrary to it.[35] *Obligatio erga omnes* literally translates to 'obligation towards everyone' which furthers *Jus cogens* in that it compels *all the states* of the international community to take legal action against wrongdoers in some situations. It is due to the fact, as stated in the Barcelona Traction case by the ICJ, that the rights are involved are so important that all States can be held to have a legal interest in their protection.[36] Accordingly, the 'obligation towards everyone' in this instance led to the outlawing of genocide and acts of aggression and developing principles to protect the basic rights of the human being, protection from racial discrimination and slavery *etc.*

Universal Jurisdiction In Different Courts Other Than The ICC

Courts of different States and some International Courts have played important roles in shedding light on and furthering the concept of universal jurisdiction for international crimes.[37] Undoubtedly, they strengthened the foundation of universal jurisdiction and rooted it firmly in international law which in turn has helped the curious mind of this author to argue in favour of

bestowing the same to the ICC with full conviction. Faryadi Zardad, an Afghan Warlord, was sentenced by the Old Bailey Criminal Court of London for conspiracy to torture and take hostages under the UN Convention against Torture of 1984 (ratified by the UK in 1988) and the British Criminal Justice Act 1988 due to Zardad's committing crimes against humanity in Afghanistan during the Taliban era in Afghanistan.[38] The convict's appeal to the British Court of Appeal was also rejected as the court affirmed the judgment provided by the Old Bailey.[39] Zardad's trial was the first in the UK that was based on the principle of universal jurisdiction where a conviction was secured at trial.[40] Zardad was first found in South London and then investigation against him was started, followed by his arrest, prosecution, trial, and conviction. Further, what Lord Goldsmith, the then Attorney General for the UK, said has added momentum to the acceptability of universal jurisdiction at national level: 'An international convention and English law allow the trial in England of anyone who has committed torture or hostage-taking'.[41]

France, for the first time applied universal jurisdiction by trying and convicting the former Mauritanian Captain Ely Ould Dah under the UN Convention against Torture 1984. He was accused of torturing two black soldiers when he was an intelligence officer in Mauritania in the context of an ethnic purge and repression led by the Mauritanian Government in the early 90s.[42] Captain Dah was arrested in July 1999 but was released under Judicial Control in September 1999, whereby he escaped and was later convicted in absentia by the French '*Cour d'assises*'.[43] This case is particularly important because on application to the European Court of Human Rights (ECtHR) by the convict, the ECtHR in deciding the admissibility of the application declared that France had universal jurisdiction to try the case and that France had

right to try Captain Dah due to the principle of *Jus Cogens* that sanctified the prohibition against torture.[44]

The first case of universal jurisdiction in the African Continent, the case of Hissene Habre is also worth noting because of its multi dimension and involvement of different countries. Hissene Habre was the former president of Chad and ruled the country until 1990 when he was ousted.[45] In 1992, the national commission of inquiry for Chad accused the Habre government of 40,000 political murders and systematic torture.[46] He had been in exile in Senegal for 10 years under nominal house arrest when in January 2000, one association (AVCRP) and seven victims filed a formal complaint against Habre in the regional tribunal of Dakar, Senegal accusing Habre for Torture and Crimes against Humanity.[47] In February 2000, Habre was charged by the Tribunal for Complicity in crimes against humanity, barbarity and acts of torture.[48] Unfortunately, on appeal, the appellate court in Senegal denied universal jurisdiction of Senegal in this case as the acts of torture were committed outside Senegal by a foreign national.[49] It decided to cancel the proceeding against Habre and the decision was upheld by the Senegal's Court of Cassation.[50]

The matter did not stop there. The UN intervened and its Committee Against Torture (CAT) issued an injunction upon Senegal not to expel Hebre from Senegal and to take all necessary measure to stop Hebre from leaving the country in order to ensure that he did not flee from prosecution.[51] Meanwhile, in November 2000, before the Court of Cassation of Senegal decided against the universal jurisdiction of Senegal,[52] while the famous Belgian universal jurisdiction legislation (War Crimes Law of Belgium) was in place, 21 victims (3 of them having already obtained Belgium Nationality) filed another complaint in Belgium against Habre.[53] In September 2005, the Belgian Judge issued an arrest warrant against Habre[54] and

requested his extradition from Senegal;[55] Habre was arrested in November 2005 in Dakar, Senegal and detained in pursuant to the warrant.[56] Unfortunately, the Appellate Court in Senegal ruled that Habre could not be extradited because of his immunity as Head of State.[57] This decision that was subject to criticism[58] because Chad had already waived the immunity;[59] Habre was thus released from detention.[60] This release provoked the CAT to rule against Senegal for violating the Convention Against Torture and to ask them either to extradite or prosecute Habre.[61] Then in January 2007, following a decision of the African Union to prosecute Habre,[62] Senegal adopted a law to prosecute crimes against humanity, genocide, war crimes, and torture[63] even if the offence is committed outside Senegal.[64] In August 2008 Chad's criminal court convicted Habre[65] and sentenced him to death in absentia due to 'undermining the constitutional order and the integrity and security of the territory'.[66]

The ICJ now came into the picture. In February 2009 Belgium instituted proceedings against Senegal in the International Court of Justice (ICJ) for the extradition of Habre.[67] The ICJ during July 2012 ruled that Senegal must prosecute or extradite Habre without further delay.[68] Relevant here is the decision of the ICJ that involves universal application of the doctrine of *Jus Cogens*: 'the Court……considers that the prohibition of torture is part of customary international law and it has become a peremptory norm (jus cogens)'.[69] The UN injunction, Belgian Prosecution, and the ICJ each applied the principle of universal jurisdiction alongside the Rome Statute. These are instances for the ICC that there are contemporary practices of universal jurisdiction in different Courts. The principle of *Jus Cogens* (peremptory norm) leads to *Obligatio Erga Omnes* i.e. an obligation towards everyone compelling all the States of International Community to take action against wrongdoer.[70] As torture can be a crime

against humanity contrary to Article 7(1)(f) of the Rome Statute, the prohibition of torture is therefore an obligation on the ICC as a forum of States. Accordingly, it shall prosecute a wrongdoer for torture when the same constitutes crime against humanity.[71]

However previously, in November 2010, the Court of Justice of the Economic Community of West African States (ECOWAS) ruled that Senegal must try Habre through an *ad hoc* or special procedure of international character.[72] The ICJ decision coupled with the ECOWAS ruling and the ruling from African Union (AU) thus compelled Senegal to establish a Court embedded in the Senegalese Justice System, [73] the Extraordinary African Chambers' (EAC).[74] Ultimately, in July 2013, the EAC formally indicted Habre for crimes against humanity, war crimes, and torture;[75] Habre was convicted on May 2016 and sentenced to life by the EAC.[76] An appeal by Habre was later rejected by the EAC.[77] The events of this case clearly portray the importance of universal jurisdiction. The first ever conviction of an African former head of State was only possible due to the fact that the universal jurisdiction played the lead role and was positively accepted by the concerned States i.e. Chad, Senegal and Belgium, the international or regional community (ECOWAS and AU) and International Courts (the ICJ and the EAC). The *Obligatio Erga Omnes (*obligation towards everyone)[78] compelled Senegal, as a member of international community to bring Habre to justice because of the *Jus Cogen* (compelling)[79] nature of the law of crimes against humanity,[80] torture,[81] and war crimes[82] perpetrated by Habre while he was in power.

The International Courts are also acting as forerunners of universal jurisdiction. The International Criminal Tribunal for Former Yugoslavia (ICTY) held in *Prosecutor vs Tadic*[83] that:

> 'Furthermore, one cannot but rejoice at the thought that, universal jurisdiction being nowadays acknowledged in the case of international crimes, a person suspected of such offences may finally be brought before an international judicial body for a dispassionate consideration of his indictment by impartial, independent and disinterested judges coming, as it happens here, from all continents of the world.'[84]

The appeal chamber of Special Court of Sierra Leone (SCSL) in the case of *Proseuctor v Kallon and Kamara*[85] held that in a case where the jurisdiction of a Court is universal, a State cannot deprive another State of its 'jurisdiction to prosecute the offender by the grant of amnesty.'[86] The principles of *Jus Cogen* and *Obligatio Erga Omnes* were beautifully applied by the SCSL where it held that the obligation to protect human dignity is '*Jus Cogen'* (peremptory norm/compelling law) and by the same token the obligation to prosecute for violation of human dignity constituting crimes is *'Obligatio Erga Omnes'* and as such Sierra Leone cannot discard such crimes by sweeping them into oblivion and forgetfulness.[87]

Further, in the legendary *Eichmann Case*,[88] the Supreme Court of Israel positively considered the proposition that the abhorrent crimes such as crimes against humanity, genocide, and torture were of such a grave nature that they constituted *delicta juris contium* (wrong against the law of nations).[89] When the case was at the District Court of Jerusalem, Israel, the District Court stated that:

> 'Therefore so far from international law negating or limiting the jurisdiction of countries with respect to such crimes, international law is, in the absence of an International Court, in need of the judicial and legislative organs of every

country to give effect to its criminal interdictions and to bring the criminals to trial. The jurisdiction to try crimes under international law is universal.'[90]

Universal Jurisdiction Before The ICC

In line with the foregoing decisions mentioned in the preceding paragraphs, it can be argued that the position of both national and international tribunals seemingly provides significant support for the ICC's right to exercise universal jurisdiction. Nonetheless, the exercise of universal jurisdiction by the ICC has not always been consistent. As already stated above, there were significant exchanges made during the inception of the ICC regarding incorporation of universal jurisdiction in the Rome Statute.[91] During the drafting stage of the Rome Statute, universal jurisdiction of ICC was argued in a broadest way by the German delegation[92] in that had it been granted to the ICC, 'pure' universal jurisdiction would have been exercised. It is because the jurisdiction would then be over any offence committed anywhere in the world irrespective of whether the alleged offender was present in the territory of a member State of the Rome Statute.[93] However, as argued above,[94] such a proposition was compromised, and Article 12 was the consequence.[95] This compromise led to serious criticisms. Scholars like Leila Nadya Sadat expressed her concern about the 'travelling tyrants' who are not covered with the current jurisdiction of ICC,[96] whereas, Hans-Peter Kaul was anxious about domestic conflict or internal war – a widely happening phenomenon in the present world[97] – where the hands of ICC are tied due to its restricted jurisdiction.[98]

When the prosecutor asked the ICC to exercise its jurisdiction in the Rohingya situation between Bangladesh and Myanmar,[99] where only Bangladesh is the State party to the Rome Statute,[100] the article 12 of the Rome Statute touching upon the question of universal jurisdiction was thoroughly considered. In this case 'the Prosecutor submitted that the reference

to 'conduct' in article 12(2)(a) of the Statute means only that 'at least one legal element of an article 5 crime' must occur on the territory of a State party'.[101] The ICC concurred with the submission of the Prosecutor on the ground that a strict reading and denial of jurisdiction in the given case would run counter to the object and purpose of the Rome Statute.[102]

The Article 7(1)(d) makes deportation or forcible transfer of a population a crime against humanity. Article 12(2)(a) states that the ICC can exercise jurisdiction if the State on the territory of which the conduct in question occurred is a member State. Now, arguably the conduct of deportation occurred in Myanmar [103] which is not a party to Rome Statute nor has it accepted the jurisdiction of ICC by lodging a declaration before the registrar in compliance with Article 12(3). However, the ICC has chosen to define the word 'deportation' in a constructive way which ultimately vested territorial jurisdiction upon it.[104] The ICC grounded its interpretation of Article 12(2)(a), so to vest territorial jurisdiction on itself, (i) on contextual interpretation that takes into account relevant rules of international law in particular the Article 31(3)(c) of the Vienna Convention on the Law of Treaties[105] and public international law and (ii) on the object and purpose of the Rome Statute.[106]

The interpretation of the word 'deportation' by the ICC is interesting because it stated that the crime of deportation is inherently trans-boundary in nature and hence an element of the crime of deportation is 'forced displacement across international borders'.[107] However, it further stated that 'the drafters of the Rome Statute did not limit the crime of deportation from one State party to another State party'[108] and the Statute 'only speaks of displacement from the area in which they (the victims) were lawfully present'.[109] As such, the ICC held that 'the inclusion of the inherently trans-boundary crime of deportation in the Statute without limitation

as to the requirement of destination'[110] reflects the intention of the drafters of the Statute to vest territorial jurisdiction on the ICC when one element of the crime is committed within the territory of a State party.

The aforesaid reading of the drafters' intention by the ICC is in fact an example of the ICC's teleological approach[111] to the Rome Statute as it extended the meaning of deportation to include its trans-boundary nature so to bring Myanmar within the Court's jurisdiction. According to a literal reading of Section 7(2)(d), if the Rohingya victims were lawfully present in Myanmar's territory, then the displacement occurred in Myanmar and hence no territorial jurisdiction could have been claimed by the ICC given that Myanmar is not a State party. Further, one can always argue, by applying the purposive interpretation, that requirement of destination was omitted from the Article 7(2)(d) because the drafters assumed that the crime of deportation can only be tried by the ICC if the 'displacement' occurs within a State party. This purposive approach in turn, is a pragmatic approach[112] as well because it serves the spirit of the Rome Statute[113] by at least bringing the perpetrators within the jurisdiction of the Court.

The Pre-Trial Chamber III has recently shed some light into the issue of territorial jurisdiction involved in the Rohingya situation through its decision pursuant to Article 15 of the Statute.[114] Even after the decision of the Pre-Trial Chamber on territorial jurisdiction, the Court felt compelled to interpret the principle of territoriality further.[115] In answering the question as to whether the Court may exercise its jurisdiction over crimes that occurred partially on the territory of a State party and partially on the territory of a non-State party the Pre-Trial Chamber addressed two issues,[116] namely (i) meaning of the term 'conduct' in article 12(2)(a) of the Statute, and (ii) location of the conduct. In addressing the former the Chamber concluded in the following terms:

> 'The legal elements of the crime of deportation require, inter alia, that the 'perpetrator deport […] by expulsion or other coercive acts'. This element may be carried out by the perpetrator either by physically removing the deportees or by coercive acts that cause them to leave the area where they were lawfully present. In such a situation, the victims' behaviour or response as a consequence of coercive environment is required to be established for the completion of the crime.'[117]

The Chamber, in line with the established principle of *actus reus* that conduct involves both act and consequence,[118] thus concluded that part of *actus reus* of the crime of deportation occurred in the territory of Bangladesh, a State party, because the crime of deportation completed when the victims crossed the border into Bangladesh due the alleged coercive acts of the perpetrators in Myanmar.[119]

Now, the reasoning and opinion of the Pre-Trial Chamber in relation to the latter issue of location of conduct provides an exhaustive summary of the Customary International Law (CIL) with regard to domestic prosecuting authorities asserting territorial jurisdiction in transboundary criminal matters.[120] The Chamber observes that CIL is the maximum the State parties to the Rome Statute could have transferred to the Court[121] and in the absence of any explicit restriction to the delegation of the territoriality principle, it is presumed that the same territorial jurisdiction the States have under international law has been transferred to the ICC.[122] In this context, the Chamber beautifully summarized five different principles of CIL developed by different States to exercise territorial jurisdiction in trans-boundary crimes[123]:

(i) the *objective territoriality principle,* according to which the State may assert territorial jurisdiction if the crime is initiated abroad but completed in the State's territory;

(ii) the *subjective* territoriality principle, according to which the State may assert territorial jurisdiction if the crime has been initiated in the State's territory but completed abroad;

(iii) the *principle of ubiquity,* according to which the State may assert territorial jurisdiction if the crime took place in whole or in part on the territory of the State irrespective of whether the part occurring on the territory is a constitutive element of the crime;

(iv) the *constitutive element theory*, according to which a State may assert territorial jurisdiction if at least one constitutive element of the crime occurred on the territory of the State; and

(v) the *effects doctrine,* according to which the State may assert territorial jurisdiction if the crime takes place outside the State territory but produces effects within the territory of the State.[124]

In line with the above principles the Chamber ruled that under CIL, even if part of the criminal conduct takes place outside its territory, States are free to assert territorial jurisdiction, as long as there is a link with their territory.[125] Accordingly, there is a clear link between the territory of Bangladesh and the act of deportation taking place in Myanmar as the alleged deportation of the Rohingyas involved the victims crossing the border. According to the Chamber this falls within objective territoriality principle, ubiquity principle and the constitutive element theory.[126] Therefore, as member States have delegated the same territorial

jurisdiction which they have under CIL to the ICC,[127] the Rohingya situation falls within the permitted limit of CIL.[128]

The aforesaid analysis has brought to the fore the fact that the ICC is interpreting the jurisdiction it has been granted as widely as possible to ensure the effective protection and realisation of International Criminal Law (ICL) standards. This in effect means that the ICC is indirectly creeping towards universal jurisdiction through broad interpretation of its territorial jurisdiction. 'True' universal jurisdiction cannot be achieved overnight. Thus, a shift towards a liberal and accommodating interpretation as demonstrated by the ICC in its decision on jurisdiction in the Rohingya situation can be a stepping-stone towards achieving the same. This liberal and accommodating interpretation vests 'quasi-universal jurisdiction' on the ICC. Despite the fact that no national of a State party allegedly committed the crime and no crime was committed, in strict and traditional sense, within the territory of a State party, the ICC nonetheless chose to extend its jurisdiction to the situation based on its reasoning that deportation is inherently trans-boundary in nature with Bangladesh being a State party at the recipient end. This reasoning has provided a logical way to bring the perpetrators to justice.

The concept of universal jurisdiction of the ICC gets further support from the aforesaid decision of the Chamber when the Chamber stated that it would be wrong to read Article 12(1)(a) in a manner so as to limit the Court's territorial jurisdiction to crimes committed exclusively in the territory of member States for the same will go against the principle of effective and good faith interpretation.[129] The Chamber further stated that there is no indication anywhere in the Rome Statute that the drafters intended to limit the territorial jurisdiction of the ICC in a manner that it can never 'hear cases involving war crimes committed in

international armed conflicts involving non-States Parties'.[130] Thus, a positive corollary is that, should the intention of the drafters of the Rome Statute and the principles of good faith and effective interpretation of the same clearly support the ICC exercising jurisdiction over non-State parties in some cases, the ICC can be said to have *Original* quasi-universal jurisdiction over non-State parties. Consequently, it suggests that successfully developing universal jurisdiction from *Original* quasi-universal Jurisdiction is highly probable through pro-active and holistic interpretation of the ICC.

The decision of the pre-trial chamber of the ICC to investigate the alleged crimes against humanity and war crimes committed during the armed conflict since 1 May 2003 in the Islamic Republic of Afghanistan,[131] as well as regarding similar crimes related to the armed conflict in Afghanistan allegedly committed in the territory of other State parties to the Rome Statute since 1 July 2002[132] is also noteworthy. The decision affirms the quasi-universal jurisdiction of the ICC; however, in the given context it denies the ICC quasi-universal jurisdiction through interpretation. The prosecutors specifically sought to investigate the alleged crimes committed by US Forces and the CIA (a non-State party) for capturing and transferring several individuals,[133] on suspicion of being members of terrorist groups to their facilities situated within the territory of State parties.[134] As per the prosecutors, the alleged crimes were committed in the context of or associated with the ongoing armed conflict in Afghanistan.[135]

In deciding the territorial jurisdiction (*Ratione Loci*), the Court's obiter dictum and findings are interesting. Although the ICC denied itself the jurisdiction to try the US Forces and members of the CIA as sought by the prosecutor for the aforesaid alleged crimes, it stated that the ICC has jurisdiction if the conduct was either completed in the territory of a State party

or if it was initiated in the territory of a State party and continued in the territory of a non-State party or vice versa (quasi-universal jurisdiction).[136] It means that if somehow a tangential link of completion or initiation of an act of torture, war crime, inhumane and degrading treatment *etc.* within the territory of a State party (or vice versa) can be shown then a non-State party can be brought to justice. Similar analogy was instrumental to bring Myanmar (non-State party) to justice in the Rohingya situation as discussed above.[137] As a result, if the torture somehow initiates in Afghanistan but resumes and completes in Guantanamo Bay or at a US Supermax Prison in Virginia then the US can be brought to justice.

However, in the Afghan scenario, some of the victims were captured or tortured outside Afghanistan on the territory of a State party.[138] These are *hors de combat*[139] persons who were captured in Afghanistan but tortured outside that country or captured outside Afghanistan.[140] Moreover, the prosecutor specifically sought that the ICC exercises its jurisdiction for that alleged torture, committed during the US detention programme, carried out by the CIA, of persons captured in the context of or associated with the armed conflict in Afghanistan having no direct link with the conflict in Afghanistan; instead, they were suspected to have link or information about the 9/11 attack on the Twin Towers.[141]

The Court found, unlike argued by the prosecution, the requirements of 'in the context of' and 'associated with' the ongoing armed conflict in Afghanistan as cumulative not alternative.[142] The Court decided that the relevant nexus between the alleged torture and the armed conflict in Afghanistan could only be satisfied if the victims were captured within the territory of Afghanistan.[143] Accordingly, those victims who were captured outside Afghanistan fell out of Court's jurisdiction for want of the aforesaid nexus. The court was reluctant to extend

the scope of international humanitarian law for non-international armed conflict, such as the one alleged by the prosecutor in Afghanistan, beyond the borders of the State where hostilities are actually taking place as per the spirit and wording of the Common Article 3 of the Geneva Conventions.[144] Further, in relation to the victims captured in Afghanistan the Court was also reluctant to exercise its jurisdiction for those alleged act of torture because the Common Article 3 is there to protect the rights and interests of those victims allegedly tortured in a non-State party within the context of non-international armed conflict.[145]

However, the Court saw the alleged conduct of 'inflicting severe physical or mental pain' separately from the act of capture and abduction that precedes torture.[146] In this manner the Court refrained itself from exercising jurisdiction for the alleged infliction of severe physical and mental pain that took place in a non-State party although the earlier capture and abduction took place in Afghanistan (a State party; and where the non-international armed conflict was taking place so to attract the Rome Statute and relevant International Humanitarian Law (IHL) and International Criminal Law (ICL) e.g. the Geneva Conventions Common Article 3).

This segregation between capture and torture is objectionable as arguably the capture and abduction that leads to ‘torture’ or ‘infliction of severe physical or mental pain’ is part of torture or infliction of severe physical or mental pain. Capture by an establishment like the CIA and abduction by the same to a foreign land itself is horrific and inflicts severe physical and mental pain. A holistic interpretation of the term ‘torture’ surely incorporates capture and abduction in it. This line of interpretation will be effective to bring the perpetrators to justice. We have already seen above, how the Chamber concluded in the Rohingya situation that States and hence the ICC are free to assert territorial jurisdiction, even if part of the criminal conduct

takes place outside its (the member States') territory, as long as there is a link with their territory.[147] Further, according to the constitutive element theory existing in CIL as stated by the Chamber[148] it can thus be argued that if earlier capture takes place in Afghanistan and then subsequent torture in a non-State party, the perpetrators of the non-State party can be tried by the ICC since one of the constitutive elements of the act of torture has been committed within the territory of a State party.

Nonetheless, the above discussion clearly portrays the pro-active approach taken by the Pre-Trial Chamber to subtly keep itself away from the ambit of universal jurisdiction. Had the Pre-Trial Chamber only decided the 'act of torture' in a holistic manner incorporating capture and abduction, the quasi-universal jurisdiction could have been exercised over the alleged crimes committed by the US, in the manner it was exercised by the Court in the Bangladesh/Myanmar situation stated above. The interesting finding of the Pre-Trial Chamber regarding the application of IHL and ICL in the context of the Rome Statute warrants attention from jurists and legal professionals alike to see whether they should be applied in the manner the Pre-Trial Chamber applied them in this present context of Afghanistan. However, the decision of the Pre-Trial Chamber of the ICC in the Afghan situation has brought the contentious matter of universal jurisdiction to the surface.

Fortunately, the decision of the Pre-Trial Chamber has been amended in appeal by the Appeals Chamber.[149] The ICC has bestowed quasi-universal jurisdiction through this act of amendment and associated reasoning. The Appeals Chamber in its judgment amended the decision of the Pre-Trial Chamber in the following terms:

> 'The 'Decision Pursuant to Article 15 of the Rome Statute on the Authorisation of an Investigation into the Situation in the Islamic Republic of Afghanistan' is amended to the effect that the Prosecutor is authorised to commence an investigation 'in relation to alleged crimes committed on the territory of Afghanistan in the period since 1 May 2003, as well as other alleged crimes that have a nexus to the armed conflict in Afghanistan and are sufficiently linked to the situation and were committed on the territory of other States parties in the period since 1 July 2002'.[150]

The reasons for the aforesaid decision have been expounded under the heading 'scope of authorization'[151] and summarised against two points, namely, (i) whether the scope of authorisation is limited to the incidents mentioned in the request and those closely linked thereto,[152] and (ii) whether certain acts committed outside Afghanistan would amount to war crimes if the victims of these acts were captured outside Afghanistan.[153]

In deciding the former point, the Appeals Chamber reasoned that the Pre-Trial chamber erred in deciding that investigation should be restricted to the incidents specifically mentioned in the Prosecutor's Request and incidents that are 'closely linked' to those incidents.[154] The Appeals Chamber reasoned that restricting so 'would erroneously inhibit the Prosecutor's truth-seeking function'.[155] It also reasoned that restricting the same, in the manner as suggested by the Pre-Trial Chamber,[156] would lead to cumbersome and unwieldy procedures[157] not required by the Rome Statute and likely to have a significant detrimental effect on the conduct of investigations.[158]

In relation to the latter point i.e. the point (ii) stated above, the Appeals Chamber decided that the Pre-Trial chamber erred in deciding that the acts in question committed by the

CIA against the victims who were captured or tortured outside Afghanistan on the territory of a State party lacked the nexus with an internal armed conflict so to trigger the application of IHL.[159] The Appeals Chamber further decided that the finding of the Pre-Trial Chamber that the 'two requirements' namely, 'associated with' and 'in the context of' are cumulative not alternative was also erroneous.[160] As the Pre-Trial Chamber based its reasoning on the *chapeau*[161] of the Article 3 of the Geneva Convention,[162] the Appeals Chamber found, in the contrary, that the interpretation of Article 3 by the Pre-Trial Chamber was incorrect.[163] The Appeals Chamber reasoned in the following terms:

> 'While it is true that the chapeau of Common Article 3 refers to an 'armed conflict not of an international character occurring in the territory of one of the High Contracting Parties', this phrase does not have the function ascribed to it by the Pre-Trial Chamber, namely to limit the applicability of the provision to the State on the territory of which the armed conflict occurs. Rather, in the view of the Appeals Chamber, it simply describes the circumstances under which Common Article 3 applies: there must be an armed conflict not of an international character in one of the States Parties to the Geneva Convention.'[164]

This reasoning of the Appeals Chamber gets support from the interpretation of Article 3 by the ICRC:

> '…which suggests that this phrase does not have the effect of restricting the application of Common Article 3 to the territory of the State in which the armed conflict occurs, but rather was aimed at ensuring that the provision would bind only those States that had ratified the Geneva Conventions.'[165]

Further, given there has been universal ratification of the Geneva Convention,[166] any armed conflict not of an international character thus cannot but take place on the territories of one of the State parties to the Convention and hence the Article 3 has lost its important in practice.[167] The Appeals Chamber not only confined itself within the *chapeau* of Article 3, it went further to consider the rest of the text of Article 3 and reasoned that Article 3 in its entirety does not suggest that the nexus required in the Rome Statute will not be fulfilled if the victims are not captured in Afghanistan or if the torture occurs outside Afghanistan.[168] It is because the sub-paragraph (1) stipulate that all those falling under the protection of Article 3 shall *in all circumstances be treated humanely* and that certain acts against these persons 'shall remain prohibited at any time and in any place whatsoever'.[169] The Appeals Chamber further opined that such an erroneous interpretation of Article 3 would frustrate the purpose of the Geneva Convention that aims at providing minimum guarantees in relation to armed conflict.[170] Consequently, the Appeals Chamber rules that merely because the alleged conduct takes place outside Afghanistan and the alleged capture did not take place in Afghanistan does not necessarily mean that the required nexus of 'in the context of' and 'have been associated with' armed conflict in Afghanistan cannot exist. A reason for this is that the non-international armed conflict can spill over to neighbouring State not party to the conflict.[171]

The aforesaid reasoning leading to the judgment amending the decision of the Pre-Trial Chamber quoted verbatim above clearly portrays that a holistic approach to interpretation can bring the alleged perpetrators (in this instance the CIA) within the vicinity of the Rome Statute and consequently, the ICC. The purposive interpretation has clearly been applied as the Court looked into the purpose of the Geneva Convention. Further, the Court considered the intrinsic aids to interpretation especially a text in its entirety as well as extrinsic material e.g. the ICRC

commentaries[172], Amici Curiae submissions[173] *etc.* to conclusively resolve the issues in question. This exercise of jurisdiction upon the alleged CIA acts of torture is an excellent instance of quasi-universal jurisdiction as the alleged crimes were not committed by any national of a State party and were not committed within the territory of a State party. This quasi-universal jurisdiction would have had greater force had the 'act of torture' been interpreted by the Appeals Chamber in a holistic manner incorporating 'capture and abduction' as argued above.

Universal jurisdiction of the ICC may become a burning issue with respect to the situation in the State of Palestine. Palestine first accepted the jurisdiction of ICC over alleged crimes committed within the territory of occupied Palestine, including East Jerusalem, from 13 June 2014 with a declaration lodged with the Registrar of the ICC on 31 December 2014 under Article 12(3) of the Rome Statute.[174] On 2 January 2015, Palestine deposited its instrument of accession to the Rome Statute[175] and on 1 April 2015 it became 123rd member of the Rome Statute through a ceremony held at the seat of the Court at The Hague.[176] The Office of the Prosecutor (OTP) of the ICC opened a preliminary examination into the situation in Palestine on 16 January 2015.[177] Then on 15 May 2018, the State of Palestine referred the Situation in Palestine from 13 June 2014 onwards to the OTP of ICC, which was formally received by them on 22 May 2018, under Article 13(a) and 14 of the Rome Statute.[178] From 24 May 2018 the matter has been pending in the Pre-Trial Chamber I of the ICC and investigation by the OTP is ongoing.

Interestingly, there were arguments coming from the realm of some liberal scholars that the Rome Statute can be interpreted liberally and selectively by allowing the ICC jurisdiction

over crimes even if the clear jurisdictional parameters are not met as the object and purpose of the ICC is to end impunity for mass crimes.[179] If seen from the perspectives of *Jus Cogen* and *Obligatio Erga Omnes,* the liberal interpretation would justify the exercise of universal jurisdiction, as they (*Jus Cogen* and *Obligatio Erga Omnes)* compel the International Community as well as the ICC to prosecute individual(s) liable for the alleged crimes committed in the occupied Palestinian territory. However, the liberal argument of the scholars was discarded by the Chief Prosecutor as '…neither good law nor makes for responsible judicial action',[180] though she did not explain why she thinks that the same is not good law.

However, after the statement was made, Palestine officially acceded to the Rome Statute and eventually became a member of the ICC; now the ICC can claim territorial jurisdiction over the crimes committed in the occupied Palestinian territory. The Prosecution has applied for an Article 19 ruling from the Pre-Trial Chamber regarding the Court's territorial Jurisdiction in Palestine over the crimes committed in the Occupied Palestinian Territory (OPT) comprising the West Bank, East Jerusalem and Gaza on 22 January 2020.[181] Accordingly, the perpetrators among the Israeli nationals and officials being nationals of a non-State party became subjected to a question of the jurisdiction of ICC.

On 5 February 2021, the Pre-Trial Chamber, by a majority, decided that the Court may exercise its criminal jurisdiction in the situation in Palestine, and that its territorial jurisdiction extends to Gaza and the West Bank, including East Jerusalem.[182] The Chamber also unanimously decided that Palestine is a state party to the Rome Statute.[183] That the decision means that the OTP has competence to investigate the alleged crimes committed in the said territory. The OTP thinks that there is a reasonable basis to proceed and that there are admissible potential cases and thus on 3 March 2021 they have confirmed the initiation of

investigation respecting the Situation in Palestine for the crimes that have allegedly been committed since 13 June 2014, the date when referral was made to the OTP by Palestine.[184] There are 43 amicus curie submissions submitted for and against the exercise of territorial jurisdiction by the ICC, which the Chamber considered in deciding its territorial jurisdiction[185] and a good number of them touched upon the question of universal jurisdiction.[186]

As the chamber has decided the Statehood of Palestine in the positive and conferred territorial jurisdiction in Palestine, it has surely broadened the existing jurisdictional horizon of the ICC. Although the same will not automatically confer universal jurisdiction on the ICC it is surely a welcome decision in that the ICC has set a precedent for the weaker states in similar footing like Palestine to seek redress through accession to the Rome Statute. An existing member state subjected to atrocities by a stronger state can start taking action in the light of Palestinian formula. In this regard, the submission of Professor John Quigley as Amici before the ICC is relevant:

> 'If Palestine's status is relevant, this Court must decide. The federal appeals court in the United States, when confronted with an issue of Palestine's status that was relevant to an insurance claim, said that the Palestinian administration in the West Bank was 'the de jure government of Palestine.' The PCIJ did the same when the issue of Palestine's status was relevant to the suit of the Greek concessionaire. Political expediency should not cause this Chamber to shirk its responsibility of equally assessing Palestine's status as a State.'[187]

As the ICC disregarded political expediency in favour of overwhelming arguments for Palestine as a state, it has made it clear to all that it is the final arbiter of its own jurisdiction. It is because defining statehood should not be seen separately from the issue of exercising jurisdiction as statehood always comes before *rationie loci* (territorial jurisdiction) where the former is a pre-condition to apply the latter. Accordingly, if there is overwhelming support in law for vesting universal jurisdiction upon the ICC, a court established to bring an end to the atrocities in the world, then the political considerations should at least become secondary to the legal considerations.

Finally, one must know that Universal jurisdiction is extra-territorial in nature.[188] Territorial jurisdiction (*Rationae Loci*) on the other hand allows the ICC jurisdiction over crimes that are committed on the territory of state parties, irrespective of the offender's nationality.[189] This 'commission of offence on the territory of state parties' has been interpreted liberally by the ICC, as we have seen above in the Rohingya situation and the Situation in Palestine,[190] enabling it jurisdiction over nationals of non-state parties thus exercising quasi-universal jurisdiction. Further, this territorial jurisdiction under Article 12 has an essence of extra-territoriality as the nationals of non-state parties can be tried by the ICC under Article 12; and objections to the same are untenable in law as expounded in the following paragraph i.e. *Lotus* principle and universal jurisdiction of the ICC.

LOTUS PRINCIPLE AND UNIVERSAL JURISDICTION OF THE ICC

The argument made above in favour of quasi-universal jurisdiction of the ICC over atrocities committed by nationals of non-party States may be opposed by different quarters on different grounds. At this juncture, support can be drawn from the *Lotus* principle/decision. The *Lotus* principle is often used to counter the US reasons for opposing the existence of the ICC.[191] The

principle was developed in the case *of S.S. Lotus (France v Turkey).*[192] Although the case related to the high seas, it has relevance to the universal jurisdiction of the ICC. In this case it was decided that if a legitimate interest in exercising jurisdiction can be shown then the burden is upon those denying the jurisdiction to prove whether any international legal rule prohibits the exercise of the same.[193] As Professor Michael P. Scharf pointed out:

> 'In the Context of the ICC, application of the *Lotus* principle would mean that sovereign States are free to collectively establish an international jurisdiction applicable to the nationals of non-party States unless it can be shown that this violates a prohibitive rule of international law.'[194]

The US Ambassador for War Crimes David J. Schaffer and Professor Madeline Morris vehemently opposed the application of Article 12 incorporating universal jurisdiction[195] arguing that i) that the *Lotus* principle is now obsolete[196] and ii) that the non-assignment principle in domestic and private international law means that exercise of jurisdiction over non-party nationals will amount to prejudice to the rights of obligor State.[197] Professor Scharf beautifully rebutted those arguments[198] with examples that prove, i) that there were recent (at the time of Professor Scharf's writing the Article) ICJ decisions[199] including even US decisions[200] accepting the continuing vitality of the *Lotus* principle; ii) that the analogy with domestic law and private international law has to be drawn very cautiously as there is no instance of incorporation of substantive principles like easements, trusts into the domain of public international law;[201] and iii) that the obligor in the case of ICC is the individual offender not the State of the offender's nationality and there is clear distinction between obliging an individual offender and it's State.[202] Accordingly, depending upon this seminal *Lotus* principle

it can be argued that the ICC can exercise jurisdiction over nationals of non-party States. As exercising jurisdiction over nationals of non-party States is a significant feature of universal jurisdiction, the *Lotus* principle strengthens ICC's claim to universal jurisdiction.

NATIONALITY AND UNIVERSAL JURISDICTION OF ICC

The ICC can only try the nationals of a State, not the State itself.[203] The issue of nationality becomes more problematic when the perpetrator belongs to a non-party State to the Rome Statute and the alleged action takes place in the territory of a non-State party. This issue has already been discussed above at length in relation to the Rohingya and Afghan Situation. However, there are certain other issues that may complicate the exercise of jurisdiction over a national of a non-State party e.g., the meaning of 'State of nationality' and 'national', the dual nationality of a perpetrator, change of nationality, refugee status[204] and Stateless persons,[205] the discussion of which are beyond the scope of the present article. The present scope and instances of application of Article 12 afford quasi-universal jurisdiction to the ICC at its best. However, if the ICC can be bestowed with true universal jurisdiction, then none of these issues will matter any longer as ICC then can try anyone irrespective of their nationality be that one of dual, single, changed, refugee *etc.*

OBJECTIONS TO UNIVERSAL JURISDICTION OF ICC AND THEIR ANSWERS

Though the Rome Statute, as a whole, faced strong opposition from States with superior military might like the US, China, and India at its very inception, however, there only appears a few objections against the universal jurisdiction of the ICC. The main objections against universal jurisdiction and their solutions are:

(i) *Objection:* Article 34 of the Vienna Convention on the Law of Treaties states, 'A treaty does not create either obligations or rights for a third State without its consent'.[206] Based on this Article the USA opposed the Rome Statute arguing that the consent of the State of the nationality of the accused is an inevitable requirement.[207]

Answer: The answer to this objection is already provided in the discussion on the *Lotus* principle above. The ICC has jurisdiction over the *nationals* of the non-party States if that national commits crime within the territory of a State party. It is not exercising jurisdiction over the non-party State/third State for it to raise any objection as such.[208]

(ii) *Objection:* Sensitive political issues will bring pressure on the ICC in general and on the prosecutor in particular.[209]

Answer: There was immense geopolitical pressure surrounding Palestine's move to join the ICC and the prosecutor's move for 'preliminary examination'.[210] Myanmar's political interest was involved when the matter was brought to ICC to try the perpetrators for atrocities against the Rohingya population.[211] There was evident US political influence surrounding investigation of crimes committed by US forces in Afghanistan.[212] The ICC is getting conversant with sensitive political issues and eventually will cope with these sort of pressures, interest and influence. The exercise of quasi-universal jurisdiction over Myanmar, the decision on jurisdiction regarding the situation in Afghanistan and the progress of the OTP regarding situations in occupied Palestinian territory bear testimony to these facts.

(iii) *Objection:* There is no duty to prosecute in international criminal law that puts an obligation on the ICC to prosecute for and punish for international crimes going beyond its territorial jurisdiction.[213]

Answer: The Rome Statute has an answer to the objection. In the preamble of the statute the contracting parties pledge that 'Affirming that the most serious crimes of concern to the international community as a whole must not go unpunished and that their effective prosecution must be ensured by taking measures at the national level and by enhancing international cooperation'.[214] Further the purpose of the Rome Statute is putting an end to impunity for those 'most serious' crimes.[215] Therefore, the crimes with which ICC is concerned are of such nature that there is a duty to prosecute for them as enshrined in the quoted passages of the preamble above. This duty gets added momentum due to the established principles of *jus cogens* and *obligatio erga omnes.*

(iv) *Objection:* Universal jurisdiction will overburden the ICC with claims that it may fail to meet;[216] the non-party State will not co-operate with the ICC to undertake the investigation for the crime.[217]

Answer: Universal jurisdiction cannot be achieved overnight. It is an incremental process. The Rome Statute already contains elements for the accomplishment of universal jurisdiction. The pro-active interpretation of those elements has the effect of bestowing quasi-universal jurisdiction. It can validly be expected that gradual practice of such interpretation coupled with widespread ratification of the Rome Statute will eventually strengthen the foothold of ICC to exercise universal jurisdiction over nationals of remaining non-party States. Further, the Security Council referral under Article 13(b), rightly termed as 'Universal Jurisdiction Lite' by Cedric Ryngaert,[218] can

also be used positively to bring most outrageous situation within the jurisdiction of ICC. The unwilling States can also be compelled through the UN mechanisms to co-operate with the ICC in investigating the crimes. Meanwhile, the resources of the OTP and the Court will continue to grow.

CONCLUDING REMARKS

It is apparent that the ICC does not have true or pure universal jurisdiction in a strict sense. But given the compelling reasons ensuing from recognised doctrines of International Law and the spirit of the Rome Statute and the pragmatic reasons of having a true International Criminal Court safeguarding the rights of the victims and acting as a major deterrent to the abhorrent crimes it can be said with conviction that the ICC should be granted true universal jurisdiction. Although there are claims that the ICC has so far exercised its jurisdiction in a biased way,[219] effectively targeting African States and ignoring allegations of war crimes committed by members of Western States, these claims are exaggerated; according to David Bosco 'there is little evidence that the prosecutor's office is animated by a political or ideological agenda, or that it has operated without regard to the relevant law and evidence'.[220] The words of Hale and Ranking provide further support when they welcomed the ICC decision on jurisdiction in the Rohingya situation and said that 'most important was its normative value – namely that it demonstrated a willingness to adhere to the law over politics and apply international criminal law as a 'standard''.[221]

However, it can be said that the ICC does have quasi-universal jurisdiction over nationals of non-State parties if the conduct in question is committed within the territory of a State party by virtue of Article 12(1)(a). The interpretation of 'Conduct committed within the

territory of a State party' can be very instrumental in this regard as already demonstrated by the ICC in the Rohingya situation and in the case of Islamic Republic of Afghanistan. Alongside liberal and purposive interpretation by the ICC of its jurisdiction, jurisdictional claims could also be secured through a revision of the Article 12(1)(a) of the Rome Statute to consolidate the existing quasi-universal jurisdiction of the court in the following manner:

> (a) The State on the territory of which the conduct in question occurred or, [*the state on the territory of which the perpetrator is found*][222] or, if the crime was committed on board a vessel or aircraft, the State of registration of that vessel or aircraft;

This will allow the ICC to try an individual of a non-party State provided they are found within the territory of a State party irrespective of them committing the alleged offence in the territory of a State party. This will retain the territorial link that exists in quasi-universal jurisdiction, will broaden the scope of quasi-universal jurisdiction and will pave the road towards bestowing true universal jurisdiction to the ICC. This will amount to a 'systematic integration', as Galand suggests, of the Rome Statute to ensure its applicability to non-party States.[223]

Further, it should not be forgotten that vesting Universal jurisdiction to the ICC also depend upon the Court's interpretation of the Rome Statute. Interpretation is crucial in this respect. It is through interpretation that the Court has been able to prove quasi-universal jurisdiction of ICC. Hence, it is expected that over time, the court will decide on issues like the Statehood of Palestine for the purpose of Rome Statute, which will empower the Court further and make it the final arbiter of its own jurisdiction so to disallow political considerations to delimit the vicinity of its jurisdiction.

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† I dedicate this article to my friend, student and brother Charles Mtonga, a wonderful soul and kind spirit, who left this earth during the outbreak of Covid – 19.

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[1] Cedric Ryngaert, 'The International Criminal Court and Universal Jurisdiction: A Fraught Relationship?' (2009) 12(4) New Criminal Law Review 498, 499.

[2] Olympia Bekou and Robert Cryer, 'The International Criminal Court and Universal Jurisdiction: A Close Encounter?' (2007) 56(1) The International and Comparative Law Quarterly 49, 51.

[3] *Ibid* 52.

[4] See the discussion on situation in Palestine and the Rohingya situation in this work.

The term 'quasi-universal' jurisdiction was also coined by Dr D. Dimitrakos of the McGeorge School of Law of the University of the Pacific in the context of ICC. He believes that the ICC has 'quasi-universal jurisdiction' because 'it (the Rome Statute) can allow the Court to assert jurisdiction in cases which could only be justified by universal jurisdiction in its most genuine form': D. Dimitrakos, 'The Principle Of Universal Jurisdiction & The International Criminal Court' (2014) Social Science Research Network 28 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2383587> accessed 20 September 2019.

[5] The Rome Statute of the International Criminal Court (Adopted at Rome on 17 July 1998, came into force on 1 July 2002) 2187 UNTS 3 (The Rome Statute).

[6] Bekou and Cryer (n 2) 53-55; US was an active opponent to universal jurisdiction of the ICC so as two other populous states i.e. China and India.

[7] William A. Schabas, *An Introduction to the International Criminal Court* (2nd edn, Cambridge University Press 2004) 74.

[8] *Ibid.*

[9] *Ibid* 75.

[10] The International Commission of Jurists (ICJ) in its lengthy report on the ICC implicitly argued for universal jurisdiction by stating that ICC should have 'inherent jurisdiction' for certain offences due to the nature of those crimes (ICJ, 1995: 27-28, 34). The Human Rights Watch (HRW) in its first comprehensive report on ICC in 1996 explicitly proposed that the ICC should have universal jurisdiction; that no state consent is required for certain cases concerning certain crimes including crimes against humanity, genocide and war crimes. The Women's Caucus for Gender Justice (WCGJ) also proposed universal jurisdiction. The International Committee of the Red Cross (ICRC) in 1997 in its paper on ICC strongly supported universal jurisdiction (ICRC, 1997b). Samoa, the first state that positively addressed the issue of universal jurisdiction of the ICC during PrepComs (Preparatory Committee Negotiations) stated that since the crimes concerned are already subjected to universal jurisdiction under Customary International Law, therefore, no state consent is necessary to try those crimes. During the PrepComs, Germany too proposed universal jurisdiction (Wilmhurst, 1999:132). In May 1998, NGOs like Amnesty International (AI) and Lawyers Committee for Human Rights (LCHR) pleaded for universal jurisdiction of the ICC with LCHR devoting a complete paper on universal jurisdiction (AI, 1998a; LCHR, 1998b). These culminated the Coalition for the International Criminal Court (CICC) to adopt universal jurisdiction as third principle in its 'Basic Principles of ICC' just before the Rome Conference (CICC, 1998a). The president of the ICRC made Universal Jurisdiction one of the main points in his address to the opening session of the Rome conference. During the Rome Conference, the European Parliament in 1998 unanimously adopted a resolution explicitly pleading for universal jurisdiction (European Parliament, 1998). According to CICC, while the German option for universal jurisdiction was not included in the Bureau Paper of the Rome Conference (Bureau Discussion Paper, 1998: Draft Art. 7), which only included the Korean, British (Original and Alternative options) and US-inspired options, 23 states were unhappy and expressed their regret in subsequent

discussions due to the exclusion of universal jurisdiction. When a bureau proposal based on the Bureau Paper were published which excluded universal jurisdiction, AI, WCGJ, HRW and LCHR appealed to the Rome Conference Jointly and Separately with AI and WCGJ arguing for universal jurisdiction (An Appeal from Four Major Human Rights Organization, 1998). The ICRC in a Separate statement also argued for universal jurisdiction (Opting in on War Crimes, 1998).

[11] *Ibid.*

[12] *Ibid.*

[13] A 'Utilitarian' approach propagated by eminent jurists Jeremy Bentham and John Stuart Mill (JSM did caveat this approach in his later work i.e. 'On Liberty') that assesses an action in terms of its consequence (greatest good for greatest number of people) is implied in this work in support of universal jurisdiction. Universal jurisdiction also gets its support from the doctrine of *Jus Cogens* and *Obligatio Erga Omnes* prevailing in International Law (see the chapter 'Universal Jurisdiction and the ICC' below). As such a utilitarian approach tells us whether an action 'should' be taken.

[14] The positive decisions rendered by the ICTY in the Case of *Prosecutor v Tadic* (See text to n 84) and by the SCSL in the case of *Prosecutor v Kallon and Kamara* (See text to n 86) firmly upholding universal jurisdiction in comparison to ICC's jurisdictional position in *the Situation of The People's Republic of Bangladesh/The Republic of the Union of Myanmar (Rohingya Issue)*(See text to n 101, 104, 105, 106) and in *the Situation of The Islamic Republic of Afghanistan* (See text to n 149, 150) bear testimony to the fact that deciding Jurisdiction is challenging for the ICC as it involves a consideration of many arguments, laws, theories and facts *etc.*

[15] Agreement for the prosecution and punishment of Major War Criminals of the European Axis and the Charter of the International Military Tribunal (IMT) (Signed on 8 August 1945, registered on 15 March 1951) 82 UNTS 279, art 6.

[16] Statute of the International Criminal Tribunal for Rwanda: United Nations Security Council (UNSC) Res 955 (8 November 1994) UN Doc S/RES/955 (1994), Annex

[17] International Criminal Court Publications, *Joining the International Criminal Court. Why Does it Matter?* page 6 <https://www.icc-cpi.int/Publications/Joining-Rome-Statute-Matters.pdf> accessed 4 April 2020

[18] Schabas (n 7) 68.

[19] The Rome Statute (n 5) Article 5.

[20] *Ibid* art 6.

[21] *Ibid* art 7.

[22] *Ibid* art 8.

[23] *Ibid* art 11.

[24] *Ibid* art 12(2)(a).

[25] *Ibid* art 12(2)(b).

[26] Schabas (n 7) 78; Situation In The Republic Of Cote D'ivoire (Decision Pursuant to Article 15 of the Rome Statute on the Authorisation of an Investigation into the Situation in the Republic of Côte d'Ivoire) Case No.: ICC-02/11 Date: 3 October 2011, para 13.

[27] The Rome Statute (n 5) art 12(3); Rules of procedure and evidence of the ICC, ICC-ASP/1/3 and Corr.1 Part II.A., rule 44.

[28] The Rome Statute (n 5) art 13(2).

[29] Aisling O'Sullivan, *Universal Jurisdiction in International Criminal Law* (First Published 2017, Routledge 2017) 89.

[30] *Ibid*.

[31] *Ibid.*

[32] Rosalyn Higgins, *Problems and Process: International Law and How We Use It* (First Published 1994, Clarendon Press Oxford 1994) 56-57.

[33] Malcolm N. Shaw, *International Law* (6th edition, Cambridge University Press 2008) 668.

[34] International Law Commission, 'Definition of a peremptory norm of general international law (jus cogens)' (Report, Seventy-first session, A/74/10, 29 April–7 June and 8 July–9 August 2019) 142 < https://undocs.org/en/A/74/10> accessed on 1 October 2019.

[35] Anthony D'Amato, 'IT'S A BIRD, IT'S A PLANE, IT'S JUS COGENS!' (2010) 6(1) Connecticut Journal of International Law 1, 3.
[36] *Barcelona Traction, Light and Power Company, Limited [Belgium v Spain (Second Phase)],* Judgment, I.C.J. Reports 1970, p. 3, [33]-[34].
[37] Peter Weiss, 'Universal Jurisdiction: Past, Present and Future' (2008) 102 (APRIL 9-12) Proceedings of the Annual Meeting (American Society of International Law) 406, 408.
[38] 'FARYADI SARWAR ZARDAD' (*Trial International*, 26 April 2016) <https://trialinternational.org/latest-post/faryadi-sarwar-zardad> accessed 25 May 2019.
[39] Regina vs Faryadi Sarwar Zardad [2007] EWCA Crim 279.
[40] 'ZARDAD' (n 38).
[41] 'Afghan Warlord Guilty of Torture' (*BBC World*, 18 April 2005) <http://news.bbc.co.uk/2/hi/uk_news/4693239.stm> accessed 25 July 2019
[42] 'ELY OULD DAH' (*Trial International,* 8 March 2012) <https://trialinternational.org/latest-post/ely-ould-dah/> accessed 25 July 2019.
[43] *Ibid.*
[44] *Ely Ould Dah v France* (2009) 48 ILM 884, 894.
[45] 'Q&A: The Case of Hissène Habré before the Extraordinary African Chambers in Senegal' (*Human Rights Watch*, 3 May 2016) <https://www.hrw.org/news/2016/05/03/qa-case-hissene-habre-extraordinary-african-chambers-senegal#2> accessed 25 July 2019.
[46] *Ibid.*
[47]'HISSENE HABRE' (*Trial International*, 29 April 2016) <https://trialinternational.org/latest-post/hissene-habre/> accessed 25 July 2019.
[48] *Ibid.*
[49] *Ibid.*
[50] *Ibid.*
[51] *Ibid.*
[52] 'Hissène Habré case, Court of Cassation, 20 March 2001' (*International Committee of the Red Cross,* 20 March 2001) <https://ihl-databases.icrc.org/applic/ihl/ihl-nat.nsf/46707c419d6bdfa24125673e00508145/90e26efa1bb31189c1256b21005549b0> accessed 25 July 2019
[53] 'Chronology of the Habre Case' (*Human Rights Watch*, 27 April 2015) <https://hrw.org/news/2015/04/27/chronology-habre-case> accessed 25 July 2019.
[54] *Ibid.*
[55] *Ibid.*
[56] *Ibid.*
[57] 'The Prosecutor vs Hissene Habre et al.' (*International Crimes Database*) <https://internationalcrimesdatabase.org/Case/761> accessed 25 July 2019.
[58] HABRE (n47).
[59] Reed Brody, 'Bringing a Dictator to Justice: The Case of Hissène Habré' (2015) 13(2) Oxford Journal of International Criminal Justice 209, 216.
[60] *Ibid* 212.
[61] *Ibid.*
[62] *Ibid*.
[63] *Ibid.*
[64] Senegal's Criminal Procedure Code (1965), as amended in 2007, Article 669.
[65] 'Chad court sentences ex-leader Habre, rebels to death' (*Reuters*, 15 August 2008) <https://reuters.com/article/us-chad-sentence/chad-court-sentences-ex-leader-habre-rebels-to-death-idUSLF73016320080815> accessed 25 July 2019.
[66] *Ibid.*
[67] Brody (n 59) 213.

[68] *Ibid.*
[69] Questions relating to the Obligation to Prosecute or Extradite
(Belgium v. Senegal) (*ICJ,* Summary of the Judgment of 20 July 2012) 12 <https://icj-cij.org/files/case-related/144/17086.pdf> accessed 27 July 2019.
[70] *Barcelona Traction* (n 36) [33].
[71] The Rome Statute (n 5) art 7(1)(f); Under the Rome Statute, torture is a crime against humanity when committed as part of a widespread or systematic attack directed against any civilian population, with knowledge of the attack
[72] Brody (n 58) 212, 213.
[73] *Ibid* 213.
[74] *Ibid*.
[75] *Ibid.*
[76] 'Hissène Habré, Chad's former dictator, just got a life sentence for crimes he committed in the 1980s' (*The Washington Post,* 1 June 2016) <https://washingtonpost.com/news/monkey-cage/wp/2016/06/01/hissene-habre-chads-former-dictator-just-got-a-life-sentence-for-crimes-he-committed-in-the-1980s/?noredirect=on> accessed on 25 July 2019>
[77] 'Court upholds life sentence for former Chad ruler Habre' (*Reuters,* 27 April 2017) <https://af.reuters.com/article/topNews/idAFKBN17T1QQ-OZATP?pageNumber=2&virtualBrandChannel=0> accessed on 25 July 2019
[78] *Barcelona Traction* (n36) [33].
[79] Peremptory Norms (n34).
[80] Rights violated in Crimes against humanity are so important that they are considered as *Jus Cogens.*
[81] The Rome Statute (n 5) art 7(1)(f).
[82] *Ibid* art 8.
[83] *Prosecutor v Tadic* (Decision on the Defence Motion for Interlocutory Appeal on Jurisdiction) (1995) IT-94-I.
[84] *Ibid* [62].
[85] *Prosecutor vs Morris Kallon and Brima Bazzy Kamara* (Decision on Challenge to Jurisdiction: Lome Accord Amnesty, 13 March 2014) (Case Nos. SCSL-2004-15-AR72(E) and SCSL-2004-16-AR72(E)) [67]-[73].
[86] *Ibid* [67].
[87] *Ibid* [71].
[88] *Attorney-General of the Government of Israel v. Eichmann* (Israel Sup. Ct. 1962), Int'l L. Rep., vol. 36.
[89] *Ibid* [12].
[90] *Attorney-General of the Government of Israel v. Eichmann* (District Court of Jerusalem, Israel, Criminal Case No. 40/61, Judgment, 11 December 1961) [12].
[91] See n 10.
[92] Philippe Kirsch and John T. Holmes, 'The Rome Conference on an International Criminal Court: The Negotiating Process' (1999) 93(1) American Journal of International Law 2, 8.
[93] Bekou and Cryer (n 2) 51.
[94] Schabas (n 7) 75.
[95] Schabas (n 7) 75.
[96] Leila N. Sadat, *The International Criminal Court and the Transformation of International Law: Justice for the New Millennium* (Transnational, New York, 2002) 118.
[97] Bekou and Cryer (n 2) 51.
[98] *Ibid* 51.
[99] *Situation in the People's Republic of Bangladesh/Republic of the Union of Myanmar* (Decision on the Prosecution's Request for a Ruling on Jurisdiction under Article 19(3) of the Statute, 6 September 2018) ICC-RoC46(3)-01/18.
[100] Bangladesh deposited its instrument of ratification of the Rome Statute with the UN Secretary General on 23 March 2010, during the resumed session of the 8th Assembly of States Parties (ASP) of the ICC that was taking place in New York. Thus it became the 111th State of the Rome Statute: People's Republic of Bangladesh

- Campaign for the Rome Statute of the ICC (parliamentarians for global action) <https://www.pgaction.org/ilhr/rome-statute/asia/bangladesh.html> accessed on 21 August 2019.

[101] *The People's Republic of Bangladesh/Republic of the Union of Myanmar* (n 99) [63].

[102] *Ibid* [70]; the ICC states 'It follows that a restrictive reading of article 12(2)(a) of the Statute, which would deny the Court's jurisdiction on the basis that one or more elements of a crime within the jurisdiction of the Court or part of such a crime was committed on the territory of a State not Party to the Statute, would not be in keeping with such an object and purpose'.

[103] 'Deportation or forcible transfer of population' means forced displacement of the persons concerned by expulsion or other coercive acts from the area in which they are lawfully present, without grounds: Article 7(2)(d) of the Rome Statute.

[104] *The People's Republic of Bangladesh/Republic of the Union of Myanmar* (n 99) [73].

[105] *Ibid* [65].

[106] *Ibid* [69].

[107] *Ibid* [71].

[108] *Ibid* [71].

[109] *Ibid* [71].

[110] *Ibid* [71].

[111] Lord Denning beautifully defined Teleological Approach in the following term: 'We had a valuable paper on it by the President of the court (Judge H. Kutscher) which is well worth studying: 'Methods of interpretation as seen by a judge at the Court of Justice, Luxembourg 1976.' They adopt a method which they call in English by strange words - at any rate they were strange to me - the 'schematic and teleological' method of interpretation. It is not really so alarming as it sounds. All it means is that the judges do not go by the literal meaning of the words or by the grammatical structure of the sentence. They go by the design or purpose which lies behind it. When they come upon a situation which is to their minds within the spirit - but not the letter - of the legislation, they solve the problem by looking at the design and purpose of the legislature - at the effect which it was sought to achieve. They then interpret the legislation so as to produce the desired effect. This means that they fill in gaps, quite unashamedly, without hesitation. They ask simply: what is the sensible way of dealing with this situation so as to give effect to the presumed purpose of the legislation? They lay down the law accordingly.' *James Buchanan & Co. Ltd. V. Babco Forwarding & Shipping (U.K.) Ltd*. - [1977] Q.B. 208, 214 (Denning MR).

[112] Pragmatic approach to statutory interpretation or pragmatic dynamism coins the idea that the meaning of a statute evolves over time; a meaning that infuses the statute with vitality and significance today. In the given situation the pragmatic approach produces the best possible and practical outcome: bringing the perpetrator to justice. This style of interpretation has been discussed by US Legislative Attorney Valerie C. Brennon in a report wherein she termed 'Dynamic Statutory Interpretation' proposed by William N. Eskridge, Jr. as 'Pragmatic Dynamism': Valerie C. Brennon, 'Statutory Interpretation: Theories, Tools, and Trends' (2018) R45153 Congressional Research Service (US Library of Congress) Report 9 <https://fas.org/sgp/crs/misc/R45153.pdf> accessed on 1 December 2019.

[113] Preamble of the Rome Statute: 'Affirming that the most serious crimes of concern to the international community as a whole must not go unpunished……Determined to put an end to impunity for the perpetrators of these crimes and thus to contribute to the prevention of such crimes…'.

[114] *Situation in the People's Republic of Bangladesh/Republic of the Union of Myanmar* (Pre-Trial Chamber III, Decision Pursuant to Article 15 of the Rome Statute on the Authorisation of an Investigation into the Situation in the People's Republic of Bangladesh/Republic of the Union of Myanmar, 14 November 2019) case no. ICC-01/19.

[115] *Ibid* [45].

[116] *Ibid* [45].

[117] *Ibid* [52].

[118] *Ibid* [50].

[119] *Ibid* [53].

[120] *Ibid* [56].
[121] *Ibid* [55].
[122] *Ibid* [60].
[123] *Ibid* [56].
[124] *Ibid* [56].
[125] *Ibid* [58].
[126] *Ibid* [62].
[127] *Ibid* [60].
[128] *Ibid* [62].
[129] *Ibid* [59].
[130] *Ibid* [60].
[131] *Situation in the Islamic Republic of Afghanistan* (Pre-Trial Chamber, Decision Pursuant to Article 15 of the Rome Statute on the Authorisation of an Investigation into the Situation in the Islamic Republic of Afghanistan, 12 April 2019) case no. ICC-02/17.
[132] 'Afghanistan, Situation in the Islamic Republic of Afghanistan, ICC-02/17, Investigation' (*International Criminal Court*) <https://icc-cpi.int/afghanistan> accessed 15 June 2020.
[133] *The Islamic Republic Of Afghanistan* (n 131)[23]; 'Annex 2C to the Request contains information to the effect that several individuals were captured, detained and transferred by US armed forces to specific US-controlled facilities (particularly, the airbases in Bagram and Kandahar), on the basis of suspicions either of being members or co-operators of Al-Qaeda, the Taliban or other associated armed groups; or of having knowledge of operations and planned attacks as well as information on these groups. Other individuals were also allegedly captured in various places and similarly mistreated inside or outside Afghanistan by the CIA, allegedly with a view to forcing confessions, obtaining information or retaliating for the attacks suffered on 11 September 2001 on US territory'.
[134] *Ibid* [53].
[135] *The Islamic Republic Of Afghanistan* (n 131) [51]: 'The Prosecutor submits that the capture of persons 'undertaken in the context of or associated with the ongoing armed conflict in Afghanistan and their later alleged mistreatment on the territory of a State Party, combine to provide the requisite nexus' (emphasis added)'.
[136] *Ibid* [50].
[137] See the discussion of n 125.
[138] *The Islamic Republic of Afghanistan* (n 131) [53].
[139] *Hors de combat* is a French term used in diplomacy and international law to refer to persons who are incapable of performing their ability to wage war. Examples include fighter pilots or aircrews parachuting from their disabled aircraft, as well as the sick, wounded, detained, or otherwise disabled.
[140] *The Islamic Republic Of Afghanistan* (n 131) [51].
[141] *Ibid.*
[142] *Ibid* [52].
[143] *Ibid* [53].
[144] *Ibid*: '...In the case of armed conflict not of an international character occurring in the territory of one of the High Contracting Parties, each Party to the conflict shall be bound to apply, as a minimum, the following provisions […]'.
[145] *Ibid* [54].
[146] *Ibid* [54].
[147] *The People's Republic of Bangladesh/Republic of the Union of Myanmar* (n 114) [58].
[148] *Ibid* [56].
[149] *Situation in the Islamic Republic of Afghanistan* (Appeals Chamber, Judgment on the appeal against the decision on the authorisation of an investigation into the situation in the Islamic Republic of Afghanistan, 5 March 2020) case no. ICC-02/17 OA4.
[150] *Ibid* 3.
[151] *Ibid* 23.

[152] *Ibid* 24.
[153] *Ibid* 28.
[154] *Ibid* [61].
[155] *Ibid* [61].
[156] *Ibid* [63] The Pre-trial chamber in restricting the incidents that are closely linked to also suggested in the alternative that investigation of incidents not closely related to those authorised would be possible if they were the subject of a new request for authorisation under article 15.
[157] *Ibid* [63].
[158] *Ibid* [63].
[159] *Ibid* [71].
[160] *Ibid* [71].
[161] Chapeau means introductory text appearing in a treaty that broadly defines its principles, objectives, and background. In the present context it is the introductory text of the Article 3.
[162] *The Islamic Republic of Afghanistan* (n 131) [53].
[163] *The Islamic Republic of Afghanistan* (n 149) [72].
[164] *Ibid* [73].
[165] *Ibid* [73].
[166] *Ibid* [73].
[167] *Ibid* [73].
[168] *Ibid* [74].
[169] *Ibid* [74].
[170] *Ibid* [74].
[171] ICRC, 'Commentary of 2016, Article 3: Conflicts not of an International Character' <https://ihl-databases.icrc.org/applic/ihl/ihl.nsf/Comment.xsp?action=openDocument&documentId=59F6CDFA490736C1C1257F7D004BA0EC> accessed 15 March 2020.
[172] *The Islamic Republic of Afghanistan* (n 149) 32, 33.
[173] *Ibid* 2.
[174] Declaration Accepting the Jurisdiction of the International Criminal Court (*International Criminal Court,* 31 December 2014) <https://www.icc-cpi.int/iccdocs/PIDS/press/Palestine_A_12-3.pdf> accessed 24 July 2019
[175] Palestine submitted the instrument with the Secretary-General of the United Nations, in accordance with article 125(2) of the Statute.
[176] 'ICC welcomes Palestine as a new State Party' (*International Criminal Court*, Press Release: 1 April 2015) <https://icc-cpi.int/Pages/item.aspx?name=pr1103> accessed 24 July 2019; It is worth noting what the Vice-President Kuniko Ozaki stated during the ceremony held on 1 April 2015: 'Accession to a treaty is, of course, just the first step. As the Rome Statute today enters into force for the State of Palestine, Palestine acquires all the rights as well as responsibilities that come with being a State Party to the Statute. These are substantive commitments, which cannot be taken lightly'.
[177] 'The Prosecutor of the International Criminal Court, Fatou Bensouda, opens a preliminary examination of the situation in Palestine' (*International Criminal Court,* Press Release: 16 January 2015) <https://www.icc-cpi.int/Pages/item.aspx?name=pr1083> accessed 25 July 2019.
[178] 'Statement by ICC Prosecutor, Mrs Fatou Bensouda, on the referral submitted by Palestine', (*International Criminal Court*, Statement : 22 May 2018) <https://www.icc-cpi.int/Pages/item.aspx?name=180522-otp-stat> accessed 24 July 2019'; the following is worth noting: '……..Specifically, pursuant to articles 13(a) and 14 of the Rome Statute of the International Criminal Court ('ICC' or 'Court'), the State of Palestine 'requests the Prosecutor to investigate, in accordance with the temporal jurisdiction of the Court, past, ongoing and future crimes within the court's jurisdiction, committed in all parts of the territory of the State of Palestine'.
[179] 'Statement of the Prosecutor of the International Criminal Court, Fatou Bensouda: The Public Deserves to know the Truth about the ICC's Jurisdiction over Palestine' (*International Criminal Court,* Statement: 2 September 2014) <https://icc-cpi.int//Pages/item.aspx?name=otp-st-14-09-02> accessed 24 July 2019; In this statement Ms. Bensouda addresses the concerns of Liberal Scholars without naming them.

[180] *Ibid.*
[181] *Situation in the State of Palestine* (Prosecution request pursuant to article 19(3) for a ruling on the Court's territorial jurisdiction in Palestine) ICC-01/18-12, 22 January 2020 <https://www.icc-cpi.int/CourtRecords/CR2020_00161.PDF> accessed on 14 March 2020.
[182] *Situation in the State of Palestine, (*Decision on the 'Prosecution request pursuant to Article 19(3) for a ruling on the Court's territorial jurisdiction in Palestine', 5 February 2020) 60, case no. ICC-01/18
[183] Ibid; Although Palestine has already become the 123rd member of the Rome Statute after following different procedures, still the prosecution's foresight as to the Chamber's opinion touching upon the issue of statehood of Palestine can be sensed from the following: 'Following the deposit of its instrument of accession with the United Nations Secretary-General pursuant to Article 125(3) on 2 January 2015, Palestine became a state party to the Rome Statute under Article 12(1). The Court need not conduct a different assessment regarding Palestine's statehood to exercise its jurisdiction in the territory of Palestine in accordance to Article 12(2)(a). Alternatively, if the Chamber deems it necessary to assess whether Palestine satisfies the criteria of statehood under international law, it could conclude that Palestine is a state under the relevant principles and rules of international law for the sole purposes of the Rome Statute', *The State of Palestine,* (n 181) [218]
[184] 'Statement of ICC Prosecutor, Fatou Bensouda, respecting an investigation of the Situation in Palestine', (*International Criminal Court,* 3 March 2021) <https://www.icc-cpi.int/Pages/item.aspx?name=210303-prosecutor-statement-investigation-palestine> accessed 17 March 2021
[185] *Situation in the State of Palestine,* Decision on the 'Prosecution request', (n 182) 2-3; the amicus curie submissions have not been considered in this Article.
[186] *Situation in the State of Palestine,* (Submission Pursuant to Rule 103 (Todd F. Buchwald and Steven J. Rapp, 16 March 2020) 21 https://legal-tools.org/doc/cktp8d/pdf/ accessed 17 March 2021; *Situation in the State of Palestine* (Observations on the question of jurisdiction pursuant to Rule 103 of the Rules of Procedure and Evidence (Professor Robert Badinter et al), 16 March 2020), 24, 25, 28, https://legal-tools.org/doc/frdqxo/pdf/ accessed 17 March 2021; *Situation in the State of Palestine* (Amicus Brief (Yael Vias Gvirsman, 16 March 2020) 5 https://legal-tools.org/doc/g2yfve/pdf/ accessed 17 March 2021.
[187] *Situation in the State of Palestine,* (Submissions Pursuant to Rule 103 (John Quigley), 3 March 2020) [60] <https://www.icc-cpi.int/CourtRecords/CR2020_00794.PDF> accessed 17 March 2021.
[188] ICRC Advisory Service on International Humanitarian Law, 'Universal jurisdiction over War Crimes' (March 2014) <https://www.icrc.org/en/download/file/1086/universal-jurisdiction-icrc-eng.pdf> accessed 17 March 2021; note that at the first column of the advice, under the heading 'state jurisdiction', universal jurisdiction has been mentioned as a 'further basis for asserting extraterritorial jurisdiction'.
[189] The Rome Statute (n 5) Art. 12(2)(a).
[190] See the discussion of footnote 119 and 182 above.
[191] Michael P. Scharf, 'The ICC's Jurisdiction over the Nationals of Non-Party sates: A Critique of the U.S. Position' (2001) 64(1) Law and Contemporary Problems 67, 72.
[192] *S.S. Lotus (Fr. v. Turk.),* 1927 P.C.I.J. (ser. A) No. 10 (Sept. 7).
[193] *Ibid* 19.
[194] Scharf (n 191) 73.
[195] *Ibid* 71-72.
[196] *Ibid* 73.
[197] *Ibid* 74.
[198] *Ibid* 73.
[199] *Legality of the Threat or Use of Nuclear Weapons*, Advisory Opinion, I.C.J. Reports 1996, 226.
[200] Scharf (n 191) 73.
[201] *Ibid* 74: There are instances of import of procedural principles from domestic law e.g. res judicata, use of circumstantial evidence *etc.* but not of substantive principles.
[202] Scharf (n 191) 75.
[203] The Rome Statute (n 5) Article 1.

[204] Zsuzsanna Deen-Racsmany, 'The Nationality of the Offender and the Jurisdiction of the International Criminal Court' (2001) 95(3) The American Journal of International Law 606, 607-615, 619 -622; this article discusses the issues at length and provides recommendations as to their solutions.
[205] Rosa Ana Alija-Fernandez, 'Justice for No-Land's Men? The United States Military Trials against Spanish Kapos in Mauthausen and Universal Jurisdiciton' in Kevin Jon Heller and Gerry Simpson (eds), *The Hidden Histories of War Crimes Trials* (First Published 2013, Oxford University Press 2013); this article discusses the application of universal jurisdiction to nationals of neutral states and stateless people.
[206] Vienna Convention on the law of treaties (with annex) (Adopted at Vienna on 23 May 1969, entered into force on 27 January 1980) United Nations, Treaty Series, vol. 1155, p. 331 <https://treaties.un.org/doc/Publication/UNTS/Volume%201155/volume-1155-I-18232-English.pdf> accessed on 15 July 2019.
[207] Sarah Babaian, *The International Criminal Court – An International Criminal World Court?* (First Published 2018, Springer International Publishing AG 2018) 26.
[208] Scharf (n 191) 74, 75.
[209] Bensouda (n 180): The existence of pressure can be sensed, however, whether the prosecutor succumbs to it is a different matter altogether.
[210] David Bosco, 'Palestine in The Hague: Justice, Geopolitics, and the International Criminal Court' (2016) 22(1) Global Governance 155, 158-159.
[211] Ronan LeeSource, 'Myanmar's Citizenship Law as State Crime: A Case for the International Criminal Court' (2019) 8(2) State Crime Journal 241, 261.
[212] Nadia Shamsi, 'The ICC: A Political Tool? How The Rome Statute Is Susceptible To The Pressures Of More Power States' (2016) 24(1) Willamette Journal of International Law and Dispute Resolution 85, 89-92.
[213] C. Tomuschat, 'The duty to prosecute international crimes committed by individuals' in H.-J. Cremer and H. Steinberger (eds.), *Tradition und Weltoffenheit des Rechts* (Springer, 2002) 315-349.
[214] The Rome Statute (n 5) Preamble.
[215] *Ibid.*
[216] Ryngaert, (n 1) 502.
[217] Bekou and Cryer (n 2) 66.
[218] Ryngaert (n 1) 503.
[219] Bosco (n 210) 169.
[220] *Ibid.*
[221] Kip Hale and Melinda Rankin, 'Extending the 'system' of international criminal law? The ICC's decision on jurisdiction over alleged deportations of Rohingya people' (2019) 73(1) 22, Australian Journal of International Affairs 26-27.
[222] Italic emphasis added.
[223] Alexandre Skander Galand, 'The Nature of the Rome Statute of the International Criminal Court (and its Amended Jurisdictional Scheme)' (2019) 17(5), Journal of International Criminal Justice 933, 956.

PHARMACEUTICALISATION AND THE LAW: THE SUFFICIENCY OF THE LEGAL FRAMEWORK TO REGULATE MEDICINAL PRODUCTS

MARIA MERKOW[*]

ABSTRACT

The overconsumption and ever-increasing dependence of society on drugs that has been vividly documented in the past decades has been described by many scholars as 'pharmaceuticalisation'; a complex social phenomenon with multiple interpretations. This article aims to analyse the legal framework concerning the drug development process up to the point of market authorisation, consequently allowing us to explore the connection between the existing legislation and the various expressions of pharmaceuticalisation.

The starting point is the scrutiny of the legal framework concerning clinical trials and the subsequent market authorisation process in relation to the public safety principle, which is considered a milestone in modern medicine and public policy at large. This effort would be, however, in vain without assessing the influence of the pharmaceutical industry on the regulator and the impact this has on delivering on the public safety principle. Finally, a case study on SSRI antidepressants is presented to illustrate the legal facilitation of pharmaceuticalisation.

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INTRODUCTION

Pharmaceuticals have been an immensely significant part of modern medicine for the past few centuries. However, the over-consumption and rising societal dependence on medicinal products has aggravated the belief that drugs can impose serious threats to human health and welfare. This phenomenon has been described by many scholars as the pharmaceuticalisation of society and has fired a heated debate on the role of drug regulation towards safeguarding public health.

There is a complex framework of legal rules regulating both clinical trials (which study the safety and efficacy of the concerned drug) and the subsequent market authorisation procedure (a prerequisite for its launch into the market). The lifecycle of pharmaceuticals does not cease at the point of authorisation**;** on the contrary**,** there is comprehensive legislation in place on the promotion and pharmacovigilance of drugs.

This article asserts that the market authorisation process plays a facilitating role concerning pharmaceuticalisation. This is linked to the failure of the regulatory authorities to adequately evaluate the drug-testing results, consequently leading to the extensive release of drugs who's safety and efficacy are not rigorously guaranteed. Therefore, the focus of this article is to precisely analyse the legal context governing the pharmaceutical development up to the licensing point. The analysis of this subject would be incomplete without considering the influence of the pharmaceutical industry on the regulator and how this essentially shapes the standards against which drugs are tested. The scrutiny of the legal framework concerning promoting strategies is beyond the scope of this article, although an overview of the marketing strategies employed is important to properly assess the impact of corporate interests operating in the aforementioned setting.

Finally, a case study of the generation of antidepressants (SSRIs) serves as an illustration of the distortion of the market authorisation process towards pharmaceuticalisation. The sales of antidepressants almost tripled in the UK after the launch of SSRIs in the 1990s and nowadays they are still amongst the most prescribed drugs in the UK.[1] However, there has been considerable dispute regarding their efficacy and safety leading us to question the judgement of the regulatory agency and most importantly its independence as regards the pharmaceutical industry. In light of these facts, corporate interests seem to be systematically prioritised over the public health objective.

PUBLIC HEALTH AND PHARMACEUTICALISATION

Dimensions of Public Health

The introduction of the NHS in 1946[2] officially established public health as an absolute imperative. In an effort to define the various dimensions of public health, commentators have been concerned with a series of key issues. The concepts of patient safety and patient-centredness have been long identified as two of the main objectives of the NHS.[3] As we shall later see, both play a significant role in relation to the phenomenon of pharmaceuticalisation.

While patient safety has been defined by the WHO as 'the prevention of errors and adverse effects to patients associated with healthcare',[4] patient-centredness is, in a sense, interwoven and sometimes indistinguishable from patient safety since treating the patient as the end of the clinical governance system presupposes their safeness.[5] However, the notion of patient-centredness is directly linked to patient autonomy: the cornerstone of modern medical ethics.[6] While being regarded as a solution to a by-gone era dominated by medical paternalism,[7] patient-centeredness has been viewed as 'an ethical panacea' encompassing medical practice.[8] Therefore, in the current autonomy-driven medical setting, patient-centeredness and their active

involvement in medical practice resulted in what was recently identified as the 'patient empowerment' movement.[9]

Patient empowerment has been interpreted as an 'equitable or fair sharing of knowledge, status and decision-making authority'[10] in the doctor-patient relationship. A change in the existing power relation between the patient and health-care professionals (HCP) in modern medicine might not be ground-breaking in the age of autonomy. Nonetheless, patient empowerment is essentially linked to a much more active and involved patient profile, that of the 'expert patient' who is responsible for their health management.[11] The empowered patient is eager andwilling to participate in the decision-making process.[12] However, in order to do so there are two prerequisites. Firstly, one needs to be informed and to have access to the relevant information to make a grounded and informed choice. On the other hand, the second prerequisite the right to choose cannot be exercised unless there is a variety of available treatments. Treating methods can take various forms and shapes, varying from the non-invasive to seriously interventive practices. Despite this broad spectrum, the intensification and industrialisation of clinical medicine during the past century has brought pharmacotherapy to the centre of attention.[13]

In light of these facts, the introduction of new medicinal products into the market is seen as a precondition of patient choice and autonomy. For this reason**,** drug licensing constitutes an essential process which can accommodate the public health interests given the fact that advancements in pharmaceuticals have been of tremendous clinical significance in the past century.[14] Yet it seems that the market has been overfilled with drugs.[15] Even though the development of pharmaceuticals is strictly regulated under EU and UK legislation, the saturation of the pharmaceutical market has led us to believe that there is a 'pill for every ill'. This idea is

suggestive of what was subsequently described by critical theorists as the pharmaceuticalisation of society.[16]

Medicalisation and Pharmaceuticalisation

Sociologists have been trying to draw attention to the 'medicalisation' of modern society for the past few decades.[17] What they have persistently attempted to describe with this term is the systemic rendering of human conditions in medical terms. This entails a gradual expansion in our understandings of diseases and illnesses which are susceptible to medical treatment.[18] The appearance of this phenomenon has been attributed to the scientific explosion that manifested itself in the industrialised world in the late 19th and 20th century.[19] As modern science was able to widely document, explain, and consequently treat symptoms and diseases, clinical medicine was given the chance to expand its jurisdiction over a plethora of issues. In turn, the increasing specialisation of knowledge over life processes reduced the ability of the lay public to comprehend their own precarious health.[20] Ivan Illich described this alienation from health as a pervasive cultural iatrogenic harm.[21]

From this perspective, the roots of medicalisation are traced back to the concentration of medical power in the hands of HCPs and the description of 'normal' experiences in medical terms. The medical profession has played a significant role in redefining what can be deemed to be normal or dysfunctional states. The constitution of the WHO endorses this approach, when defining health as 'a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity'.[22] While adopting a broader definition about what is regarded as an illness can be a very successful technique in that direction, this has been more cynically described as disease-mongering.[23] Such methods have been employed in the case of psychiatric

disorders, such as anxiety and depression,[24] which are the focus of the forthcoming case study analysis.

The reconstruction of human conditions as *pharmaceutical matters* is, to an extent, the aftermath of medicalisation.[25] Pharmaceuticalisation 'denotes the translation or transformation of human conditions, capabilities and capacities into opportunities for pharmaceutical intervention'.[26] Critics argue that the over-reliance on pharmaceuticals could have severely detrimental consequences for public health.[27] Despite the degree of overlap between the two concepts, this analysis is nowadays considered to be somewhat trite, since it identifies the medical profession as the central driver of both phenomena but obscures the influence of other major parameters.

What solidifies the complexity of these matters is the fact that medicalisation and pharmaceuticalisation do not always unfold simultaneously, and when they do this might not be due to disease-mongering.[28] To use an illustrative example: Ritalin is a stimulant medication prescribed for treating children diagnosed with attention-deficit- hyperactivity-disorder (ADHD) and was first introduced as such in the 1960s. While there was a significant growth rate in Ritalin prescriptions in the 1990s, which can be attributed to the medicalisation of ADHD,[29] John Abraham claims that this was not only due to increased diagnosis. Instead, he proposes the broader shift from psychotherapy to drug treatment and direct-to-consumer-advertising (DTCA) as possible explanations for the amplification in Ritalin prescriptions.[30] Abraham also argues that patterns of drug-reclassification of prescription-only medicines (POMs) to over-the-counter (OTC) products, magnifies the use of pharmaceuticals. Hence, the degree of pharmaceuticalisation observed is, in many cases, independent from the expansion of medicalisation as it does not involve the transformation of a non-medical condition into a medical one.[31]

This narrative substantially suggests the introduction of novel factors into the existing equation, most notably that the way that pharmaceuticals are regulated, can have an influence over patterns of increased consumption. however, unfortunately an in-depth analysis of all the driving forces of pharmaceuticalisation is beyond the scope of this article. There is extensive discourse on the sociological facets of this phenomenon amongst which are the 'demand side', i.e. patients and patient organisations, and the growing influence of the pharma-industry on the market.[32] Yet identifying the relevant legal aspects and how these impact or even accommodate this ever-growing social dependency on pharmaceuticals seems to be a neglected area. As the main objective of this attempt is to highlight the legal context of pharmaceuticalisation, an analysis of the Market Authorisation Regulatory Framework[33] for medicinal products and the highly relevant Clinical Trial Regulation[34] (which regulates the launch of new drugs into the market) is deemed essential.

FROM BENCH TO BEDSIDE: THE DEVELOPMENT OF MEDICINAL PRODUCTS

As mentioned above, the introduction of new pharmaceutical products is a common interest for both the public and, of course, the manufacturing companies. However, according to the House of Commons Health Committee Report on the Influence of the Pharmaceutical Industry, it is also State agents (such as the UK Government) that take an interest in the process. This has varied explanations. Primarily, the excessive consumption of drugs has a direct impact on the NHS budget allocation while also being responsible for a series of drug-induced illnesses and harm, such as adverse drug reactions (ADR). Except for affecting hospital admissions and health expenditure in general, ADRs also embody the second reason of state interest in the process, which is the aforementioned patient safety objective.[35]

The Sufficiency of the Legal Framework to Regulate Medical Products

However, the UK Government is also concerned with maintaining the status of the pharmaceutical industry, which has been described as 'a jewel in the crown of the UK economy'.[36] Besides being the third most profitable business nationwide,[37] the UK pharma-industry is accountable for 10% of world pharmaceutical expenditure, while funding 65% of domestic health-related R&D.[38] In order to strike a balance between these conflicting interests the medicine processes from 'bench to bedside' are strictly monitored and regulated.

The Medicine Processes

The procedure of drug development commences with the selection of a New Molecular Entity (NME), i.e. an innovative active ingredient. Testing begins with pre-clinical toxicological and pharmacological studies in animals and human cells. Their successful completion leads to the conduct of clinical trials on humans, initially on healthy volunteers (Phase I) and afterwards on a small patient group afflicted with the target disease, which measures the efficacy of the researched compound (Phase II). In Phase III the studied population may rise to 10,000 patients, measuring the efficacy and safety of the product on a larger scale. The compound is compared against a placebo or against an already licensed product when generic drugs are researched, or non-inferiority trials are conducted.[39] The derived data forms the basis of license applications. If the drug is licensed, post-marketing trials are conducted to study the long-term safety and efficacy of the medicines. The post-marketing surveillance (Phase IV) of a drug might include additional clinical trials heeding for reported ADRs while observing how the medicine works in 'the real world'. Therefore, participants encompass a broader patient spectrum, such as pregnant women and patients with co-morbidities.[40]

The Regulatory Framework

In order to evaluate the shifts in pharmaceuticalisation and attempt to draw a connection between its purported driving forces, it is vital to acknowledge that these interact within the existing regulatory framework. Despite the complexity of this phenomenon, which is undeniably shaped throughout the aforementioned medicine processes, the clinical trial stages and the marketing authorisation procedure itself are in the spotlight of this analysis. This selection will allow an examination of the market authorisation framework, which would be in vain without the clinical trials insight given that they generate the licensing application data.

REGULATING CLINICAL TRIALS

The Clinical Trials Directive and Clinical Trials Regulation

The primary interest of the legal framework regulating clinical trials is to ensure the safety of the participants, considering the long history of abusive experimentation on humans.[41] Following the ethical principles set in the Nuremberg Code[42] and the Declaration of Helsinki[43] this concept is further diffused in the Clinical Trials Directive (CTD)[44] which has been embedded into national law by the Medicines for Human Use (Clinical Trials) Regulations 2004.[45] In 2014, the European Commission introduced the Clinical Trials Regulation (CTR),[46] which is still being implemented. Both instruments focus on protecting the 'participant's welfare[47] through a risk/benefit calculation, which ensures that the researched subject is not worse off for being involved than they would have been otherwise'.[48]

Apart from that, clinical trials have a facilitating role for the 'pharmaceutical development pipeline'. Considering the cost and duration of this process, during which the data for the marketing authorisation application are derived, it is no wonder that the main clinical trial sponsor (the pharma-industry) is under pressure to present a positive profile for the researched medicine. In that setting, the CTD requires Member States to introduce monitoring mechanisms

and set standards for the Good Clinical Practice of clinical trials,[49] therefore, ensuring the robustness and reliability of the drug-testing results.[50]

At this point, it is vital to state that EU legislation, especially in the form of Regulations with direct effect[51] instead of Directives, can achieve a much-needed legislative harmonisation between Member States in relation to the internal market where new drugs will be released.[52] However, disparities in the implementation of the CTD into Member States' domestic legislation were considered to be a hurdle for both the scientific community and the pharma-industry, hence, the introduction of a Regulation to replace the CTD was prioritised.[53]

Among others, the most significant changes under the CTR include the introduction of an EU portal,[54] which will centralise the submission of the application for the authorisation of the clinical trial and that of the EU database[55] that will store both the application data and the reported results. Hence, there is significant progress towards increased transparency as research protocols[56] and obtained data on safety and efficacy[57] will be made publicly accessible.[58]

Nonetheless, serious concerns link the adoption of the CTR with the promotion of central EU policies rather than ensuring the reliability of the reported outcomes. Following Mark Flear's sceptical approach, the CTR is substantially used as a means towards stimulating research and innovation in Europe, the outcomes of which can later facilitate the active and healthy ageing of the European population, a programmatic priority of the European Commission.[59] While this can be viewed as a sustainable way to tackle one of Europe's biggest problems- its rapidly ageing population - Flear suggests that the CTR in conjunction with EU research initiatives, such as 'Horizon 2020',[60] essentially provide the legal uniformity and funding opportunities that will lead to the launch of marketable pharmaceuticals.

In that sense, the CTR is used as a vehicle for delivering on the European integration and competitiveness goals, while catering for the needs of the pharma-industry.[61] Contrary to Recital 82 of the CTR that declares that both the internal market objective and the common safety concerns (as expressed through the clinical trials' standards) are of equal value, the practical application of the CTR feeds into a narrative of economic growth, which can conflict with public health and patient safety.

The Efficacy Standard

This belief is further supported considering that clinical trials' standards mirror the market authorisation criteria, which are discussed in further detail later. Against this background, clinical trials investigate the safety and efficacy of the researched compound.[62]

Double-blind Randomised Control Trials (RCT) including the experimental drug, a placebo, and an active control (i.e. a drug with a similar active ingredient) are considered to be the scientific gold-standard according to non-binding guidance issued by the European Medicines Agency (EMA).[63] Even though active control trials are to be preferred in cases where there is a safety concern linked to the experimental medicine, or where treatments of inferior efficacy prove to be harmful to those participating in the trial, the EMA concludes that the granting of market authorisation depends solely on demonstrating a favourable 'risk/benefit' profile for the experimental medicine. On that account, the researched drug does not need to establish its superiority to the established medicine in terms of efficacy.

The alignment of the clinical trial standards with the market authorisation criteria has drawn considerable criticism.[64] Concerns about the subordination of public health to market

interests are justified as the legal context neglects comparative efficacy and the high degree of market saturation. In order to fully comprehend the sufficiency of the existing regulatory framework as regards safeguarding public health and assess whether the corporate bias hypothesis has merit, it is crucial to observe how the clinical trials' outcomes are presented and disseminated in practice.

Conflicts of Interest and Dissemination of Clinical Trials' Results

Although the main target of the clinical trials regulatory framework is for them to generate robust and accurate data, which will lead to the licensing process, there is growing evidence that the reported results do not reflect the reality.

Considering that pharmaceutical companies are relying on drug sales to recoup their R&D expenditures, it is no wonder that they also fund 90% of clinical trials in the UK.[65] Despite this being a necessary step for drug development, the existence of major conflicts of interest in industry-sponsored studies is inevitable.[66] The allocation of funding for independent research from the Department of Health[67] along with the Research Ethics Committees' and Institutional Review Boards' scrutiny on the proposed protocols are the most prominent ways to suppress biased outcomes in relation to clinical trials. However, in the current state of affairs, the main way to manage the conflicting interests is through the dissemination of the reported results, part of which is the publication process.

Transparency, which is the prerequisite principal, translates into the author's obligation to disclose any funding they have received from the sponsor of the trial. While readers may be more sceptical when interpreting an industry-sponsored trial unfortunately there are still justified concerns about disclosure's insufficiency to stop the pharma-industry from shaping research.[68]

Except for researchers 'selectively emphasising' the positive outcomes of trials,[69] the misinterpretation of clinical trials' results is usually linked to the deliberate design of trials by sponsors. Relevant literature has brought to surface a plethora of methods to draw attention to the positive traits of the researched compound. Placebo-controlled trials and trials using no therapy as a comparator have been distinguished as the best way to deliver on efficacy standards, explaining why they have been largely favoured by the pharma-industry.[70] Moreover, the selection of inappropriate therapeutic agents as active comparators,[71] such as drugs whose efficacy has been proved to be of minor significance is a standard method. [72]

Substandard comparisons in industry-sponsored trials can also result when different administration methods[73] and dosages[74] are used between the experimental and the established drug. In addition to that, selecting 'treatment naïve subjects' (i.e. people who have not used medication to treat their condition in the past) has also proved to be a successful technique, given that the effect of the experimental medicine is accentuated on treatment naïve subjects in comparison to those accustomed to treatment.

Distorted trial design, as explained above, is just a part of the bigger picture since empirical studies have been able to demonstrate that reporting of trials' results is frequently not only partial but also biased and inconsistent with the original research protocols.[75] Even more significantly, clinical trials with positive results have higher chances of being published. This phenomenon is later discussed in further detail in relation to clinical studies on antidepressants, however, what meta-analyses suggest is that data on licensing applications do not exactly match those published in the scientific press.[76]

Considering the relevant legislation, Article 37(4) of the CTR imposes an obligation on the sponsor to report the trial's outcomes within a year of completion, irrespective of its outcomes.

When coupled with Article 81 which mandates that result summaries understandable to a layperson shall be made available in the EU database and Recital 67 of the CTR which presupposes that a trial is registered in the EU portal before being started, one is under the impression that there has been significant advance towards a more transparent and controlled framework.

However, in practice scientific progress is disseminated through seminars, scientific publications, and journals rather than personal research on clinical trials' registries. While clinical trial sponsors are not under a legal obligation to publish the results in the scientific literature, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) encourages the submission of clinical trials' results for publication in peer-reviewed journals.[77] Self-regulating practices have been long used within the pharmaceutical industry for such issues, though their efficacy is highly doubted.[78]

This essentially means that the only way to safeguard the integrity of the published data is through peer-reviewing the manuscripts submitted for publication. The scope of this process is, nevertheless, rather limited given the fact that significant information about relevant studies may be withheld from the editors.[79] In addition to that, editors are not really expected to replicate the trial in question, thus confining their role to being merely advisory.

Conclusions

The regulation of clinical trials is constitutive for drug development and licensing. There have been significant efforts towards establishing a more transparent framework under the CTR, which will 'restrain' the influence of the pharmaceutical industry in demonstrating the drug- testing data in a favourable way; consequently, favouring the public health objective. Nonetheless, the

impression gained is that corporate interests are coordinated with the EU agenda, hence compounding an already existing problem: the power of the pharmaceutical industry. The convergent clinical trials' and market authorisation standards are proof that the pre-licensing process is steered towards the launch of new medicinal products, whose efficacy is highly doubted, rather than defending public interests.

MARKET AUTHORISATION

Given that the clinical trials stage is completed, pharmaceutical companies proceed to apply for market authorisation. The granting of market authorisation is a prerequisite for the launch of the concerned drug into the market,[80] therefore, playing a facilitating role for the pharma- industry and the public as well. As Emily Jackson comments, market authorisation works for drugs as an 'official badge of reliability, which prescribers rely upon when deciding whether to prescribe it to their patients'.[81] This observation sums up the rationale behind the introduction of the market authorisation framework *per se*, which primarily aims to safeguard public health.[82]

The need to regulate the pharmaceutical industry and promote safe medications became stronger with the Thalidomide tragedy,[83] which urged the Parliament of the UK to introduce legislation.[84] Nonetheless, more than half a century later the patient safety principle is still not absolute in that context as the development of the pharma-industry has also been emphasised in the relevant legislation.[85] Before assessing the aftermath of the regulatory process, it is essential to examine the existing market authorisation framework as it has been shaped by the EU legislation.

Regulating the Market Authorisation Procedure

European legislation offers a number of parallel routes for medicinal products to be licensed. In that setting, the existing framework introduces a centralised European institution whose jurisdiction includes EU Member States and the countries of the European Economic Area (EEA), alongside which Member States are allowed to operate a competent, national authority.

Considering the centralised procedure, Regulation (EC) 726/2004 of the European Parliament and Council (The Regulation)[86] sets the standards for the function of the European Medicines Agency (EMA), which handles the authorisation, supervision and post-licensing pharmacovigilance procedures for both human and veterinary medicinal products.[87] Under this procedure, the applicant submits a single application directly to the EMA. Once the market authorisation is granted, it is valid within the EU/EEA countries.[88] Despite comprising just an option for drugs with a novel active ingredient,[89] the centralised procedure is compulsory among others for drugs targeting cancer, diabetes and neurodegenerative disorders.[90]

Article 12(1) of the Regulation provides that Community market authorisation is to be granted insofar as the applicant has demonstrated the quality, safety and efficacy of the drug in question and is valid for five years.[91] As mentioned above, applicants intending to place a medicinal product on the market of the EU Member States have the option to apply for simultaneous national market authorisations in the various countries they are interested in.[92] The EU has issued Directive (EC) 2001/83 governing the authorisation of medicinal products by national authorities,[93] which the Human Medicines Regulations 2012 have transposed into domestic legislation. The UK counterpart of the EMA is the Medicines and Healthcare Products Regulatory Agency (MHRA).

In accordance with the EMA scientific process[94] and within 210 days from the submission date of the application,[95] national authorities proceed to examine the safety, efficacy and quality

of the drug.[96] Quality standards of the manufacturing method are assessed against the Good Manufacturing Practice requirements.[97] The safety and efficacy standards are measured and decided upon the clinical trials' data,[98] as supplied by the manufacturer, meaning that the regulator is highly unlikely to directly analyse raw data from the trials' stage. [99]

Moreover, the classification of the concerned drug as a POM or OTC also needs to be considered by the regulator during the licensing procedure.[100] Regulation 62 of the HMR refers to the maximum daily dose, the product's strength and packaging as indicative criteria which the MHRA has to consider when proceeding with this decision. The existing regulatory framework is in place to ensure that novel products are sufficiently tested before they are launched into the market. Nevertheless, the only information available about their action has been generated in the controlled environment of clinical trials. Hence, the regulator guards against the expected or unexpected ADRs through the classification process.

In that sense, prescribers[101] have been described as the gatekeepers of POM,[102] which are deemed to be the products with the highest risk of danger and are often authorized under conditions.[103] On the other hand, products considered to be reasonably safe when supplied without the supervision of a pharmacist are classified as General Sales List (GSL).[104] However, POM drugs can be reclassified as OTC at a later point, provided the regulator has sufficient data regarding their safety to be used in a less controlled environment.[105] While this process has proved to be a major relief for the NHS budget, leading to fewer GP appointments, as mentioned above, drug declassification is identified as one of the key drivers of pharmaceuticalisation.[106]

Except for providing a coherent framework for the operation of the national regulatory agencies, the Directive introduced the 'mutual recognition procedure'.[107] According to this, EU Member States with a pending licensing application of a drug which is already authorised in a

different EU country can validate the original authorisation instead of proceeding with an individual assessment.[108] Member States are strongly encouraged under Recital 12 of the Directive to recognise the original authorisation, unless there are serious grounds which link the concerned drug with a risk to public health.[109]

It is obvious that EU legislation sets the ground that will allow the various national regulatory authorities to function in a consistent manner. Nonetheless, the uniformity across the political frameworks that govern the licensing process has caused serious concerns regarding the influence of the pharma-industry on the regulatory schemes which is deemed to undermine their efficiency to deliver on the public health goal.

The Harmonisation of Scientific Standards

As mentioned above, the approximation of the Member States' legal frameworks relating to the drug development process has been a priority for the EU. This objective is persistently highlighted in the Directive's Recitals. Despite defining public health as the essential aim behind the regulation of medicinal products,[110] the legislator proceeds to declare that this objective shall not hinder the development of the pharma-industry and the free circulation of its products within the internal market.[111] Therefore, any obstacles suspected to impede the launch and movement of medicinal products are to be removed.[112]

In that setting the introduction of CTR in 2014 accommodates what seems to be an already homogenous market authorisation scheme across European countries. The operation of a centralised agency as a pan-European regulator is a milestone in that direction. However, the harmonisation of scientific standards globally and the influence of the pharma-industry in shaping those are more concerning.

The harmonisation of the scientific standards in the licensing process has been accentuated by the industry's influence. Pharmaceutical companies around the globe have organised the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), a non-profit organisation aiming to 'promote public health through the international harmonisation of technical requirements'.[113] The ICH was founded by the European, Japanese and American pharmaceutical industry associations, along with the regulatory agencies of the aforementioned countries. In addition to the original members, the ICH has expanded to include further members and observers, consequently widening the forum for dialogue.[114]

The influence of the ICH is tremendous considering that once ICH standards are adopted, they are binding for the participant regulatory agencies, amongst which is the MHRA.[115] Moreover, there is a tendency for non-participant regulatory agencies to adopt the ICH standards. In that context, the pharmaceutical industry has used the ICH as a means to renegotiate the scientific criteria against which the 'risk/benefit' calculation is evaluated; therefore, promoting its interests.[116] This process has proved, however, to be detrimental for patient safety in various instances, as in diminishing the duration of carcinogenicity testing in clinical trials, during which serious ADRs of the tested drug are studied.[117] Instead of encouraging regulators to demand data of the highest standards based on which the licensing application will be decided, the ICH has repeatedly endorsed less safe options in order to accomplish the above-mentioned uniformity.

Competition and the Capture of the Regulatory Agency

The influence of the pharma-industry has also been linked to the rise of competition among the various regulatory authorities, which once again is exploited in favour of corporate interests.

Starting with the strict time frames imposed by the Directive, which the regulatory authorities must obey upon delivering their judgement, it is evident that time-efficiency is an extremely important element in the process. This rationale has also been expressed by the pharma-industry which lobbied the European Commission to introduce the mutual recognition procedure.[118] Since a short time-lag between application and authorisation translates into millions' worth of losses for the pharmaceutical companies, it is only logical to observe that insofar as the mutual recognition procedure is an option, manufacturers will opt to apply to the Member States with the shortest waiting times.[119] Coupled with the fact that regulatory agencies are funded by the licensing fees,[120] it is no wonder that they find themselves in a competitive position with each other.

'Agency Shopping' has led approval times to significantly dropping in the European territory,[121] while in the UK the MHRA, whose activities are solely funded by the pharma-industry's licensing and annual service fees, holds a processing-time record, dropping waiting times from 70 to 30 within a year.[122]

In that respect, the European framework is substantially pressuring the regulatory agencies to approve drugs and be fast when doing so. At the other end of the continuum, speedy processes can prove detrimental for public safety, given that the thorough examination of applications is sacrificed in favour of time efficiency. The lack of additional criteria which could eliminate any safety-related concerns seems only to compound the existing problem; therefore, forcing the regulators to place significantly more trust in the industry when assessing the clinical trials' data.[123]

Although the mutual recognition procedure might have aggravated competitiveness between the regulatory agencies, the adjustment of the regulator to the industry's standards is no news. Abraham documents a series of gradual shifts during the past fifty years, illustrating that the regulatory authority is continuously altering its standards to meet the desires of the pharma- industry.[124] Targeting to maintain the high levels of developmental work conducted in the British territory, the regulators essentially adopted the industry's perspective, despite the fact that drugs came to the UK market faster than in the USA and the major European countries.[125]

In this light one is under the impression that the relationship of the regulator with the industry is a very close one. The validity of this contention is highlighted by regular interchanges of staff between the two,[126] which to an extent is only natural, given that regulatory authorities seek to recruit adequately trained and informed scientists to evaluate the drug-testing data.

On the other hand, these findings cause suspicion regarding the arising conflicts of interest. Commentators have described this two-way flow between the industry and the regulator as the 'revolving door' phenomenon, meaning that a lot of regulatory officials begin their career in the pharma-industry, then work for the regulator before being promoted back to their initial employment environment.[127] Studies on the existing policies concerning conflicts of interest have showed that disclosure of interest in pharmaceutical companies is currently a normative prerequisite for scientific experts' participation in drug-regulation decision-making.[128]

The impartiality of the participating members is central for both the MHRA[129] and the EMA.[130] According to the Code of Practice for Chairmen of the Commission on Human Medicines, which is the responsible MHRA body for the regulation of drugs targeting human diseases, chairs and members can disclose their interests within three months of the day of their appointment.

These declarations are also publicly accessible, therefore, enhancing the transparency and reliability of the agency. During this period, conflicted members are expected to abstain from meetings and voting.[131] It is particularly significant to mention that both agencies seem to be confident that the mere declaration is sufficient for the concerned expert to be deemed non-conflicted in the future,[132] even though evidence shows that more than 25% of experts involved in both the UK and European regulatory agencies display interests in the pharma-industry.[133]

Consequently, the belief that the regulatory authority is 'captured' by the industry seems to be valid. Abraham has argued that 'the regulators too often consistently award industry the benefit of scientific doubt when reviewing products' in relevance to the highly technical 'risk/benefit' assessment of novel drugs. Unfortunately, this finding has been confirmed by the House of Commons Report, which claims that raw data are to be analysed only when there are serious concerns about the misrepresentation of the reported results.[134] Drug testing results are surrounded by secrecy, therefore, leading us to question the regulator's independence and competence to effectively audit the submitted data. Thus, the failure of the regulator to set the bar high enough creates the ideal environment for the amplification of pharmaceuticalisation.

Conclusions

It is important to acknowledge that legislation, regarding the market authorisation of medicinal products provides thorough guidance on the licensing procedure, as it is repeatedly underscored that licensing applications are decided based upon the safety, efficacy and quality of the concerned drug. However, the sufficiency of the regulator to safeguard patient safety is doubted in practice, since the relationship between the regulator and the industry seems to be too close. This allows for the development of agreed-upon processes and regular interchanges of staff between the two;

therefore, justifying the relaxed scrutiny on the drug-testing data.[135] The effect these practices have on public health is, however, magnified once the concerned drug is licensed.

PROMOTING STRATEGIES REGULATION

The granting of market authorisation is a turning point for the pharmaceutical companies, given that the concerned drug can subsequently be promoted. Promoting strategies are of paramount significance in order to recoup the R&D investment; therefore, it is no wonder that the pharma-industry spends almost twice the R&D budget for marketing purposes.[136]

Advertising practices of medicinal products are also subject to legislation. Part 14 of the HMR regulates the advertising of medicines to the lay public and prescribers as well. The MHRA acts once again as a supervisor; nonetheless, the control of marketing strategies for drugs in the UK has been traditionally a result of self-regulation, in accordance with the relevant European Legislation.[137] The ABPI Code of Practice which is administered by the Prescription Medicines Code of Practice Authority (PMCPA), an independent ABPI body, is a relevant example.[138]

Primarily, the advertisement of drugs that are either sold under the supervision of pharmacists or are classified as GSL is legal, provided that the information supplied is not misleading.[139] Although the DTCA of POM is strictly prohibited,[140] license holders are still able to employ a plethora of alternative marketing practices.

Promotion to Prescribers and Patient Organisations

In fact, the pharma-industry has found a different target group to promote licensed POM: the prescribers themselves.[141] Although physicians deny being influenced by marketing activities, one cannot overstress the impact of such methods on their prescribing habits.[142] Routine practices include the organisation of industry-sponsored scientific conferences[143] and the

recruitment of 'Key Opinion Leaders' (KOL), those being acclaimed scientists participating as spokespersons in the aforementioned events or presenting research papers.[144]

Yet KOLs have more to offer than scientific insight, since building relationships with the lay media[145] in order to present a positive profile of the marketed drug constitutes a major part of their tasks. This has become even more diffuse with the explosion in online content creation and the diversification of media outlets supplying the public.

Similarly, the pharma-industry has repeatedly funded patient advocacy groups, such as third- sector patient organisations.[146] Patient groups have constructive roles in health policy. This is partly due to what Nikolas Rose defines as 'biological citizenship', when describing the process of identification through one's biological senses, such as health or more precisely the lack of it.[147] Besides provoking the individual's engagement with the alleged disease in terms of patient empowerment, 'biological citizenship' can have a collectivising effect, thus embodying the demand to improve the health and well-being of a particular patient population.[148] The rise of the HIV/AIDS activist movement is a prominent example, also demonstrating that patient groups' interests are sometimes coordinated with the corporate agenda. While initially targeting the education of the public and combating the stigma, HIV/AIDS activism allied itself to the pharma-industry when demanding further research and treatment for the disease.[149]

Although recruiting KOL and funding patient organisations are not illegal per se, such payments are not always transparent.[150] There has been a recent advancement considering reporting drug company payments to patient organisations, as members of the ABPI are obliged to disclose their payments on ABPIs online database named Disclosure UK.[151] Analyses of the submitted data revealed the big-pharma companies' dominance in the funding landscape, whose contributions were steered towards boosting 'advocacy, campaigning and disease awareness' of

conditions *with higher commercial viability*.[152] While patient organisations cannot deny the publication of these data,[153] HCP are protected under the EU privacy law, therefore, able to refuse the declaration of certain payments or opt-out entirely.[154]

What these strategies have in common is their ability to 'market the disease' instead of marketing the treatment, hence successfully circumventing DTCA. However, this has proved to be an extremely successful way of indirect marketing, since the released drug is marketed as an answer to the promoted illness.

THE CASE OF SSRIS

At this point using a case study to illustrate the above-mentioned phenomena appears to be highly useful. Although pharmaceuticalisation encompasses modern medicine and the social perception towards drugs at large, there is a trend to be observed in the developed countries regarding psychiatric and lifestyle drugs. This hypothesis is verified by the Public Health England analysis of NHS prescription data, indicating that in 2018 17% of the adult population received and has dispensed one or more prescriptions for antidepressants.[155] The introduction of antidepressants such as Prozac, Paxil and Seroxat, of the Selective Serotonin Reuptake Inhibitor (SSRI) class, in the 1990s led prescriptions to triple within a decade.

In that sense choosing to elaborate on psychiatric drugs and SSRI antidepressants in particular, serves a two-fold role. Primarily this relates to the demonstration of a rather Western perception of psychiatric medications and their action. Furthermore, the SSRI example offers us the chance to evaluate the adequacy of the clinical trials and market authorisation frameworks, which is stressed by the promoting strategies that were employed at a post-licensing point.

The Disease-Centred Model of Drug Action in Psychiatry

The Sufficiency of the Legal Framework to Regulate Medical Products

In order to assess the regulation of currently used psychiatric drugs, having an overview of the relevant historical background is highly important. The majority of currently used medicines in psychiatry were introduced after the 1950s.[156] Until that point and for a considerable period afterwards treatment for the 'psychologically ill' was mostly confined to notorious physical treatments, such as insulin coma, lobotomy and ECT by the late 19th and early 20th century.[157] Commentators have linked the drastic shift to drug prescription in psychiatry with the need to relieve asylums, which at that point were congested with an increasing number of chronic conditions.[158] What Joanna Moncrieff refers to as the 'disease-centred' model for the action of drugs, appears to be a valuable justifying base in legitimising drug treatment for mental malaise.

Moncrieff elaborately describes the 'disease-centred' model as the assumption that drugs and chemical compounds 'are thought to act on the underlying physical disease process'.[159] In that sense antidepressants are considered to directly act on the pathology of depression; therefore, providing a suitable alternative to the aforementioned physical therapies that were just as disease-specific as modern drugs.

The shift to the 'disease-centred' model in psychiatry came as no surprise as it followed the above-mentioned corpus of scientific and technologic data of the early 20th century.[160] This will mark a new era in modern medicine, as the symptomatology of the purported disease will be identified in anatomical and psychological terms,[161] therefore, allowing for the broader establishment of the medical profession and its jurisdiction.

From Anxiety to Depression

Both the rise of a symptomatic model, specifically defining each disease, and the parallel search for a disease-specific treatment have particular merit in the case of depression and the promotion of SSRIs as a suitable treatment. Depression is nowadays considered to be the second greatest

source of disability on the planet,[162] affecting about 10% of the world population. This is indicative of a bigger trend, i.e. the increase in diagnosis of mental health conditions, which has been also the case of ADHD mentioned in previous chapters. However, this was not always the case.

Even though melancholia, the precursor of depression, was commonly diagnosed in the past, in the dawn of the 20th century depression was considered to afflict mostly severe instances, which were usually treated with ECT.[163] On the contrary, the modern concept of depression initially appears in the 1950s. This shift was accompanied by the introduction of the first drugs that were referred to as antidepressants.[164] Despite being used in psychiatric practice at the time, the prescription of antidepressants remained rather limited until the 1990s since antidepressants were thought to be suitable only for quite severe cases.

The Systemisation of Diagnosis and Disease-Specific Treatment

Instead, a different diagnosis was gaining popularity at the time. Anxiety and panic had been two of the most common diagnoses before the rise of depression. As the introduction of the third edition of the Diagnostic and Statistical Manual (DSM-III) in the 1980s proposed the reorganisation of the classification system within psychiatry,[165] the description and perception of psychiatric illnesses became evidently systemised. In addition to establishing a symptomatic descriptive model of psychiatric diseases, the DSM-III essentially fragmented what was considered to be 'a monolithic entity into a number of discrete disorders such as panic disorder, obsessive-compulsive disorder, social phobia, posttraumatic stress disorder and generalised anxiety disorder'.[166]

Following this shift in diagnosis, the population of patients suffering from anxiety grew significantly while the sales and promotion of drugs like Xanax and Valium, which are tranquilising

agents of the benzodiazepine group, as disease-specific treatments were culminating.[167] This is an example of medicalisation and pharmaceuticalisation unfolding proportionately, as the overdiagnosis was followed by excessive prescribing practices. DTCA contributed to the amplification of both phenomena, as this is also valid and commonly practiced in the USA, and it is argued that this shapes how the public conceptualises health problems whilst medicalising emotions, such as anxiety.[168]

This becomes apparent considering that women have persistently been the main target group and also users of psychotropic medications. The pharmaceutical industry took advantage of the disproportionate female consumption of tranquilisers to promote Valium as the 'Mother's Little Helper', which promised to help mothers approach the calm and euphoric, middle-class housewife archetype, suggestive of the 1960s ideals.[169]

Despite the initial enthusiasm, evidence presented in the 1980s linked the consumption of benzodiazepines with physical dependence.[170] The House of Commons Report mentions the over-prescription of benzodiazepines and the spread of severe ADRs, such as seizures and hallucinations, as a 'good illustration of the dangers of drug promotion and…under-regulation or over-reliance on industry self-regulation'.[171] The emergence of ADRs is relatively expected after the launch of a new product, nonetheless, benzodiazepines were authorised despite the lack of evidence supporting their efficacy in the first place.[172]

While the severity of ADRs linked to benzodiazepines caused a wave of distrust towards tranquilisers in general, the pharma-industry responded with the 'relaunch' of antidepressants. Despite being available since the 1950s, their relaunch as a non-addictive solution proved to be an ideal quick fix for the market crisis.[173] In that setting, the new generation of antidepressants also known as SSRIs was widely introduced with the release of Prozac by Eli Lilly in 1987.

Marketing SSRIs: The Creation of a New Market for Depression

In order to create this new market for depression, the pharma-industry, instead of just promoting the new medicinal product, focused on promoting depression itself. Psychiatrist David Healy observes the rise of a significant body of relevant scientific literature in the late 1980s, while research on depression and the dissemination of its outcomes became a primary target for the pharma-industry.[174] Similar to the case of Viagra,[175] celebrities were employed as spokespeople, targeting the lay public in countries allowing DTCA. What is, however, shocking is that pharmaceutical companies were commissioning scientific articles from well- established researchers, recruited as KOL, aiming to reshape the academic viewpoint on depression.

Well-known promoting practices such as the organisation of scientific symposia, or the offer of 'free lunches'[176] were mainly employed to steer the medical opinion towards perceiving depression as an under- or misdiagnosed disease, affecting a bigger percentage of the population. Moreover, the extensively used technique of 'ghost-writing', which included the modification of scientific manuscripts in order to include the commercial points of the company in question, accentuated this effect; therefore, promoting the prescription of antidepressants.[177] Furthermore, the majority of the big-pharma companies use medical writing agencies while trying to deliver the desired information, while there is considerable evidence of efforts towards diminishing any negative press on the issue.[178]

Targeting a Female Audience

As regards practices aiming the lay public, the 'chemical imbalance' theory worked once again as a stepping-stone. Eli Lilly's initial campaign on Prozac used the characteristic phrase: 'Like arthritis or diabetes, depression is a physical illness'.[179] This idea was recreated in subsequent advertising campaigns in the 2000s which echoed that:

> '…a growing amount of evidence supports the view that people with depression have an imbalance of the brain's neurotransmitters…many scientists believe that an imbalance in serotonin may be an important factor in the development and severity of depression.'[180]

Besides propagating the chemical imbalance theory, traditional promotional strategies included the creation of a 'patient profile' that people could relate to. Even though adopting a genderised agenda that could consequently limit the drug's target audience was not a priority, as mentioned above, the majority of antidepressants' consumers happen to be women.[181] This fact has been indirectly exploited as Blum and Stracuzzi have reported, since a considerable part of the scientific discourse and articles on Prozac diffusely portray a female user.

The underlying idea behind this ostensibly legitimate practice proves to be rather troublesome. Except for latent messages referring to women with chemical imbalances, articles on Prozac promote a new female profile, much different to the Valium-portrayed sedated housewife. While embracing a shift in the modern female reality, the promoted narrative is still a deeply stereotypical one. In that context, Prozac accounts for the driven, successful, high earner mother.[182] Besides endorsing the neoliberal cliché of highly productive individuals, this illustration is primarily unethical as it adds the element of a masculine-typed detachment in the bigger picture.[183] Unfortunately, this misguided representation of femininity ends up feeding into the vicious cycle of antidepressants' sales, as the majority of real-life women is unable to live up to these unrealistic standards.

Moreover, at a time when Prozac was about to come off patent, women and the female physiology were once again in the spotlight; therefore, endorsing the above-described pattern of gendered marketing practices. Fluoxetine, the active ingredient in Prozac was rebranded as Sarafem, a specific treatment for the premenstrual dysphoric disorder. Sarafem was granted a

patent until 2007 increasing the chances to offset huge losses from Prozac's generic competitors.[184] This effort was so meticulously orchestrated that even the dominant colours in Prozac's packaging (green-blue) were altered to what was deemed a more feminine design (pink-purple). Moreover, in countries allowing the DTCA of POM, one observed the trend to include much younger women in advertisements. While some decades ago depression was a rare disease for the middle-aged, by the late 1990s women in their mid-twenties appeared in depression advertisements.[185]

Promoting Biomedical Literacy

Since DTCA is prohibited in the UK,[186] disease awareness campaigns and the dissemination of self-educational material on the Internet have constituted a very effective alternative. Among others, questionnaires in drug companies' websites indicating the 'right' psychiatric disorder according to the submitted answer have gained surging popularity.[187]

The active engagement of corporate stakeholders with the self-education of patients is linked to patient empowerment and the emergence of the Internet as a pluralistic means of enhancing biomedical literacy.[188] The use of 'biologically coloured language' which is employed to shape one's self-understanding, is not solely disseminated through authoritative channels, such as medical advice. Instead, it is diffused through pharma-companies' webpages and educative campaigns.[189] Therefore, the empowered patient learns about depression through a

prearranged set of information, which does not really allow them to consciously self-manage their health condition.[190]

In the UK during the 1990s, the industry-sponsored 'Defeat Depression Campaign' was ran by the Royal College of Psychiatrists and targeted both HCP and lay people. While emphasising that SSRIs do not cause dependency, the campaign affected prescribing rates and the public's perception of depression immensely. Dr Des Spence's comment on the over-prescription of antidepressants is the epitome of pharmaceuticalisation since it depicts 'a whole generation of people coming up who almost feel that being unhappy is an abnormal state, which it is not'.[191]

'Risk/Benefit' Assessment of SSRIs

As described in chapter five, the market authorisation safety and efficacy criteria are measured against the 'risk/benefit' profile of the examined pharmaceutical agent, derived from the clinical trials' data. As regards antidepressants over a thousand RCTs have been published displaying their unshakable beneficial impact on the disease's physiology. However, a meta- analysis of the FDA[192] licensing data on 12 antidepressant medications primarily showed that a plethora of negative trials remained unpublished, selectively reported or were presented in a positive manner, which essentially alters their claimed efficacy rate to being of clinical marginal significance.[193]

The widespread conflict of interests among scientific researchers, the pharma-industry and the academic community has been continuously reported in biomedical research;[194] nonetheless, antidepressants appear to be a rather murky case. This hypothesis is primarily supported by the antidepressant-placebo difference in efficacy scores which proved to be almost non-existent.[195] Moreover, these differences are amplified in RCTs that are conducted on severely depressed patients, which have been favoured when testing SSRIs. Except for the fact

that the average antidepressant consumer is not a severely depressed patient,[196] choosing to research extreme cases leads to favourable results as '…antidepressant efficacy is attributable to decreased responsiveness to placebo, among very severely depressed patients, rather than to increased responsiveness in medication.'.[197]

This fact is evidence that the market is flooded with ineffective treatments, therefore, making us question the adequacy of the existent regulatory framework and its efficacy standards. Nonetheless, this concern in not limited to the efficacy criteria. Masking unfavourable results, such as reports on the sexual side effects of SSRIs is one form of misrepresenting drug-testing results.[198] However, this is relatively insignificant when compared to withdrawal symptoms[199] and higher suicidality rates amongst adolescents that have been linked to Seroxat and Prozac respectively.[200]

The MHRA set up an independent Expert Working Group (EWG) also including lay people to report on the issue[201] which concluded that there was a significant lack of data in the initial licensing application, such as excluded data derived from trials operated outside the USA on Prozac-related suicidality. Despite these findings, the concerned drugs were authorised.[202] On the other hand, data indicating that 30% of participants in Seroxat clinical trials experienced withdrawal symptoms, which the regulator had access to were found to be overlooked.[203] The EWG identified a substantial risk of severe withdrawal reactions, while mitigating the SSRI-induced suicidality risk in adults.

This area still remains unclear and newer studies suggest a modestly increased rate of suicidality in adolescents.[204] The lack of certainty does not, however, justify the cover up of such a finding which is not only unprofessional and unethical but also highly relevant to the nature of

the researched medication, considering that suicidal desires are deemed to be symptoms of the depression.

Moreover, the positive reaction to antidepressant consumption has proved to be a short-term outcome, as relapsing patterns are more often observed in patients who are on antidepressant medication, therefore, increasing the liability of recurrence.[205] This tendency is inevitably aggravated by the fact that antidepressant consumers are less likely to undergo psychotherapy.[206] While the incentives behind this rather personal choice are not perfectly clear, Conrad argues that the promotion of pharmacotherapy might instead be a part of the administrative agenda.[207]

Having an overview of SSRI promoting strategies, i.e. how the market for depression emerged, establishing the transition in the diagnostic trends would seem to be self-evident. Notwithstanding, the opponents of this viewpoint argue that the shift from anxiety to depression came as result of a more thorough and scientific approach in psychiatry which was signified with more accurate diagnostic skills.[208]

This comment is, however, not validated by prescription rates. With the launch of SSRIs the sales of antidepressants almost tripled within a decade in the UK. In addition, the sales of tranquilisers which were used as an anxiety treatment plummeted,[209] consequently verifying the hypothesis that antidepressants essentially took over the 'anxiety market'. This approach is further endorsed as SSRIs are being prescribed instead of anxiolytics, while being recommended as a treatment to various diseases of the anxiety spectrum.[210]

Conclusions

Conclusively the chosen case highlights the failure of the regulatory framework to ensure patient safety when licensing drugs that are not only inefficient but also detrimental to public health. According to the aforementioned House of Commons Report, only 5% of depression prescriptions target severe depression.[211] Shall we then assume that the rest of the prescribing practices are treating unhappy and distressed people with unnecessary and possibly dangerous medications? The cases of tranquilisers followed by SSRI antidepressants suggest that aggressive marketing strategies are indeed rewarding and that self-regulation does not work well within the industry, contrary to the ABPI statement.[212]

CONCLUSION

To conclude**,** it is justified to say that the continuously growing consumption and dependence on medicinal products cannot be viewed as a necessary evil following the intensification and industrialisation which dominate modern medicine. While pharmaceuticalisation may be partially attributed to the rather general shift towards patient empowerment and patient choice in the medical setting, evidence alludes to the fact that there is more to this than meets the eye.

This assertion is primarily due to what seems to be insufficient regulation regarding medicinal products throughout their development process. Despite the extensive legislation regulating the oversight of clinical trials, the pharmaceutical industry appears to be in a position of power considering its ability to structure the drug-testing process so that it will demonstrate a favourable outcome and subsequently the dissemination or often suppression of the resulting data. Moreover, the alignment of the clinical data standards, considering safety and efficacy in particular, with the market authorisation criteria indicate that the clinical trials' phase is steered towards the licensing of new drugs rather than safeguarding patient safety.

This hypothesis is further endorsed when assessing the operation of the regulator itself. Regulatory agencies rely upon drug-testing data derived from the clinical trials stage in order to approve market authorisation applications. Since most clinical trials are industry-sponsored there is a significant possibility that reported results are skewed or that negative reporting trials are not even part of the submitted market authorisation file. Mindful of this reality, regulatory agencies should set a high bar during the evaluation procedure. Notwithstanding, the EWG's report SSRIs illustrated that this is not followed in practice since the regulator was aware of significant ADRs despite which the concerned drug was licensed.

The prioritisation of corporate interests in detriment of public health in drug regulation is further supported given the reported two-way exchange of staff between the regulator and the pharmaceutical industry, which leads us to question the sufficiency of the existent policy regarding the declaration of conflicts of interest.

Moreover, the overview of the strategies used to promote the licensed drugs suggests that aggressive marketing encourages pharmaceuticalisation. The 'marketing of depression' through largely industry-funded campaigns run either by patient organisations or medical associations is suggestive of the influence of the pharmaceutical industry. In fact, concepts highly relevant to patient empowerment and choice, such as biomedical self-literacy have been exploited in order to spread an excessively consumeristic mentality towards health and well- being but also towards medicinal products *per se*.

In this context, patient choice can be viewed as a neoliberal tool, reforming health in economic terms and consequently introducing market mechanisms into the provision of publicly funded services.[213] While there has been significant improvement considering the transparency of drug regulatory procedures, evidence shows that efforts targeting to engage with the

empowered patient in the drug development process are still aligned with corporate interests; therefore the regulator is only paying lip service to the safety and involvement of the empowered patient. As it has been veritably stated in the House of Commons Report the regulator cannot serve two masters;[214] hence, there is still a long way to in order to truly deliver on public health and safety.

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[188] *Ibid* 149.
[189] *Ibid* 148.
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Interview with Avocate Linda Weil-Curiel

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Saint-Germain-des-Prés, Paris

Linda Mururu*

Linda Weil-Curiel is a French advocate and women's rights activist. Because of her legal work and activism, countless young girls in France were saved from undergoing female sexual mutilation. Her efforts led to the many excision trials brought before the Assizes Court in Paris in the 1980s onwards, whereby excisers and parents who committed the crime were brought to justice. France is cited as the leading European country in FGM prosecution, what many don't know is Ms. Weil-Curiel was the linchpin behind the success.

LM: When did you first learn about female genital mutilation (FGM)?

LWC: In 1982 I belonged to the feminist movement founded by Simone de Beauvoir. We had a meeting and a fellow feminist friend brought a newspaper with an article about a 3 month-old baby girl (Bobo Traoré) who'd died from bleeding after undergoing a procedure endorsed by her parents. The baby bled a lot but the father had refused to call a doctor. Instead of healing, the baby died. The father not knowing what to do with the little corpse took her to hospital as if she were alive.

The doctor checked the baby but couldn't explain her sudden death until he took off the diaper and found clotted blood where there should have been the lips and clitoris. When the father was questioned he refused to explain what had happened to his child. The death not being 'natural' on any account, the doctor withheld the permit to bury the body and conducted an autopsy. The awful truth was discovered after the small corpse was found devoid of blood. It was heart-rendering.

There was a police investigation and the father was called for questioning. He admitted that the cutter came and his wife held the baby while she was cut. The bleeding would not stop but he was afraid to take the baby to hospital because he knew what they had done was forbidden in France.

LM: How did the father know it was forbidden?

LWC: I discovered there had been a similar case about 18 months earlier that had had no publicity. I didn't know of this other case as excision was all very new in France. It was heard in the lower court at the *Tribunal Correctionnel*. The exciser was given a one-year suspended sentence but all the African communities heard what had happened in court. This is why the father said he knew it was forbidden and didn't want to answer questions.

LM: Was there a specific law enacted against FGM?

LWC: A group was gathered at the Ministry for Women Affairs to find a solution after those early cases were reported. Doctors were called and I was the only lawyer invited because it was known that I had begun fighting the mutilation of infants. I was asked if a law was needed. I answered, 'We have the penal code which forbids and punishes mutilation. Why should we need a special law, a law which would be like a pointing a finger to the African people in France. Should we write a law, it would be against them, to punish them. Our system is that the law applies to everyone in the French territory. In that regard the law is universal.'

LM: What was the legal position on FGM at the time (1982-1983)?

LWC: Legally, mutilation is a crime hence it should be brought before the highest criminal court (*Cour d'assises*). However, the first two cases reported were treated by the prosecutor as a misdemeanour: parents claiming to have followed their tradition couldn't have wanted to harm their child. Nonetheless they didn't seek help and go to hospital early enough to save the child.

I refused that what had been done to the child be treated as a misdemeanour. If one cuts off the penis it's a crime because you chop off someone's organ that is functional: it is a mutilation. So why turn a blind eye when it's a baby girl's clitoris and labia that have been cut off? Moreover when the victim is a black child exposed to a cruel tradition who needs protection?

But speaking of parents some would say, 'It is their culture, they cannot read, they don't speak French, they didn't know it was forbidden here, the father only wanted what is best for his child, etc.'

My views were different; though they pretend to be ignorant men know the purpose of the practise. Men in particular blame it on the women, 'It's a woman's affair. Anyway, I was at my job!'. It is only in one of the earlier cases that the father took the blame to protect his wife.

He said he did it for his daughter's sake: because she has been cut, later she will behave and be marriageable.

LM: Do you refer to it as female genital mutilation in France?

LWC: In France we don't call it FGM but *excision*. To excise is to cut. I insisted we also call it female sexual mutilation because the true aim of the act is to deny the woman her own sexuality, her feelings, her desires. If she has no sexual desire she will not look for another man, she will be obedient. Her femininity, her strength and independence have been ripped off. Men say, what I have in between my legs is my strength; they know what is in between a woman's legs is also her strength. Women too are entitled to sexual pleasure. If it were a question of culture, why don't they cut off the tip of the ear as a mark of the culture? It would not interfere with the functioning of the ear. So you see the target is the woman's sexuality.

LM: Is it okay to call it female circumcision?

LWC: Definitely not. It is misleading. It likens it to male circumcision. Men could think, well, what is the problem? We're circumcised so why do women make a fuss about it? But it's not the same. It is mutilation.

I went to the United Nations for the Commission on the Status of Women (CSW) conference many times, around the nineties. The Inter-African Committee (IAC) called the mutilation "a harmful traditional practice". But how do you expect women from other parts of the world to understand that it is a practice that involves chopping off female sexual parts? So I said that in my view, you have to name it for what it is – it is mutilating women. People began to say FGM. In French we say *excision* or female sexual mutilation because *genital* does not have the same meaning regarding female sexuality. It is the sexuality that is aimed at.

LM: What was the reaction to excision in France?

LWC: People didn't know what this act referred to, except maybe doctors and those who had lived in practising countries. It is so unthinkable to do that to a child that people could not even imagine it was a widely practised tradition.

The newspapers got very interested in the matter because it was so new. A journalist titled her article – IS EXCISION A MISDEMEANOUR IN FRANCE? It angered one of the highest magistrates in France who six months earlier had issued a ruling that cutting female sexual parts being a mutilation is, legally, a crime. That case involved a white French woman from Brittany who had cut off her daughter's clitoris and labia. She had no links with African communities. She was just a violent woman.

She was sent to the *Cour d'assises* for committing the same crime that African mothers do. I argued excision cases involving African women must also be prosecuted as a criminal act because although there is the cultural element, it is still the same act. Of course tradition will come as an extenuating circumstance.

In our legal system we have three courts. The *Tribunal de Police* for petty crimes, the *Tribunal Correctionnel* for offences classified as misdemeanours, and the *Cour d'assises* or Assize court the highest criminal court. In the Assize Court there are three judges (the president and two assessors) and a jury. Every party has their say, the prosecutor closes and asks for the penalty. The judges and the jurors sit together and examine the case completely. They hold a vote and a verdict is reached. After the judgement is read the jurors leave the court and the judges hold the civil hearing. The lawyers for the victim ask for compensation and the judges decide upon it. So altogether we have decided the case in its entirety – both criminal and civil.

LM: Did you get involved in the Bobo Traoré trial?

LWC: Yes. I stepped in as a *partie civile* on behalf of an association – CAMS (*Commission pour l'Abolition des Mutilations Sexuelles*). You see, the parents being the accused, an association can join the case in favour of the child. The *partie civile* is a particularity of our legal system. It's not like amicus curiae because a *partie civile* has the same rights as the victim in the trial. This is how I got involved in all the excision trials.

LM: What were your arguments in the trial?

LWC: I objected to the judge's reasoning. It could not be a misdemeanour because legally a criminal act was committed. The child was held down and someone sliced off her genitals. If your hand is cut off it's a mutilation and it is severely punished. So in Bobo Traoré's case before the charge of not going to hospital, the parents are guilty of mutilation or assisting with the mutilation.

LM: How do legal proceedings commence in France?

LWC: All public officers are obliged to inform the prosecutor (or the police) of any crime they are aware of. After investigating the facts the police write a report and send it to the prosecutor who decides whether there is a case to answer. If there is a case it could go two ways. If it is a simple case the prosecutor sends the case directly to court.

If it is complicated and needs further investigations the case is sent to the investigating judge. The judge has full powers to investigate. The judge will ask the family, assisted by a lawyer, to give their explanations and can instruct the police to conduct further investigations. Once this process is complete the judge then decides to which court the case will be sent. As a civil party I have access to the dossier and I argued that the case could only be brought before the *Cour d'Assises* for trial.

LM: Did you face opposition?

LWC: At first everybody was against me. The press reported the cases and it was becoming very harsh for the families. Doctors said they had informed the mothers that excision was illegal but some were not in favour of parents being tried in court. I insisted mutilation was a crime and we are governed by a law that applies to everyone on French soil, moreover it protects children who cannot have their say. On the whole, families were very angry with me because I disclosed their secret practice.

Awa Thiam, a Senegalese academic and activist, the founder of CAMS, had written a book in 1978 'Speak Out, Black Sisters'. She wrote about the violence that African women endured and among which was excision. She was very well known and would accompany me to court. She would testify that excision was harmful, that the law needed to be enforced to protect children and that African women were now aware of the consequences of excision and did not want it any longer.

Eventually African activists understood my stance and became less hostile. In particular Khady Koita. She said, 'What Linda is doing, is in order to protect our children'. They understood that my work and my siding with the law was not out of hate; we were adversaries but not enemies.

LM: Did you as a white woman understand why these African women were at first hostile?

LWC: I understand they were not pleased that I would criticise their custom and have them facing court. But what does the custom mean once you have settled in France and began raising children here?

Mothers very often did not wish to cut their daughters because they remembered how they had suffered. In the *Cour d'Assises* everyone is listened to and has their say. The trial is didactic and after it is over people are not the same, they have learnt something. Many African women came to testify and explain how excision ruined their lives. Some said, 'I have no sexual enjoyment, I am bored during sex with my husband. I just stare at the ceiling and wait for him to be done. It hurts me so much; excision has deprived me of my womanhood.'

LM: Was there cultural sensitivity?

LWC: It was difficult in the beginning. The matter was becoming very sensitive because people didn't want to accuse black parents of being bad parents. And it was also very political due to ongoing immigration from former French colonies.

But the crime does not cease to exist because it is cultural. And from the start families were informed that excision is not tolerated in France.

I argued in court that custom cannot take the place of the law. You cannot argue 'it is my custom' when it is against the law. And especially when it is maiming a defenceless child. The law protects all children whatever their origin.

LM: How were families informed that excision was illegal?

LWC: One way was through the Protection Maternelle Infantile (PMI) services. They are medical and social centres that are free for all mothers with children from age 0-6. African mothers loved going there because they could socialise with other mothers. One explained to me that she liked going there because when the husband left for work he would lock her in the house, unplug and take the telephone with him. So going to the PMI was very welcome.

The PMI doctors would inform the mothers that excision is illegal and that if they did it to their daughters they would be taken to court.

Then parents began taking their daughters abroad to be cut but when they came back they were prosecuted because whether here or in Africa, the child is still under the protection of France. So some families abandoned the practice.

LM: Did doctors report cases of excision?

LWC: In the beginning they were not reporting because they did not want the mothers to go to court. So the regional doctor called me to come and explain the law to them. In the criminal code if a civil servant notices that a child under 15 years has been ill-treated they must report it.

I said to the doctors, 'If you see that a child has been beaten isn't it your duty to report to the authorities that the child needs protection?'

Yes of course, they agreed.

Isn't it the same with excision? I asked.

They grumbled… it's different, foreign customs, religion, blah blah.

So I asked them, are you favourable to excision doctors?

Of course not, they said.

We know that you inform the mothers that excision is forbidden in France. But if you see they have nonetheless done it, will you report it?

Often the doctor is embarrassed and grumbles reluctantly.

If you have explained to the mother that not only is it illegal, but also detrimental to the health and well-being of her daughter, yet you see she has done it anyway and you don't report it, as the mothers talk amongst themselves, they will think, 'the doctor said not to do it, but I did it, he has seen it and nothing happened.' So everyone in the vicinity will think, 'they tell us not to do it, that we risk prison, but when they see it, they don't do anything, so let's continue.'

So I said to the doctors, it is you now who endangers the next little girl in that family because you kept silent. What will you say to these girls when they come to you years later and ask, 'You could have prevented my mutilation and I hold you responsible for what happened to me'.

LM: After that meeting did the doctors begin to report?

LWC: There wouldn't have been all those trials if they did not report. But who knows how many went unreported, especially those that happened outside of Paris and its vicinity.

I was in Paris and the only lawyer to take the burden on my shoulders. It was very time consuming and costly for my practice because I did it pro bono. I also produced a CD, *'Exciser c'est pas bon'* by Bafing Kul, a Malian singer who sought asylum in France after being threatened

for singing against the practice. I also produced a film 'Bintou in Paris', with English sub-titles. I am a feminist and I don't accept that women should be treated like that.

LM: Out of all the cases, which one in particular stands out?

LWC: The most infamous case was heard in 1999. The exciser, Hawa Gréou, was charged with committing 48 excisions and 25 parents were charged as accomplices. The case was reported by a victim, Mariatou. She was cut as a young girl but reported it when she turned 18 after leaving her family.

The day she was cut her mother told her and her sisters she was taking them to the doctor for a vaccine. They went to a flat where there were other women and little girls. At some point the women asked who would be the first and it was decided it was to be Mariatou's sister. She entered the room and suddenly there were terrible screams. Mariatou thought that maybe the doctor was a bit rough giving the vaccine and had hurt her sister's sore finger. The sister was sobbing when she came out.

It was Mariatou's turn. The women held her down on the floor covered with a plastic sheet that was wet with blood. She screamed in pain and cried knowing her sisters were next. They all were cut, their mother watching. When back home, the social worker came to visit and Mariatou tugged at her sleeve wanting to tell her what had happened. Her aunt saw what was about to happen and whisked her away warning her to never talk about it, that it was forbidden.

It was only at school during a lesson when the teacher mentioned that in some countries it is a custom to cut girls, that Mariatou finally understood what had happened to her and her sisters. She also recalled seeing razor blades upon her parent's bed. Once, before she left for school, Mariatou saw mothers come in with babies. Mariatou had a baby sister and she begged her mother to spare the baby, but when she came back from school the baby had been cut. She said she would never forgive her mother.

Mariatou decided she would leave her family when she turned 18. As she was nearing her 18th birthday her father said it was time for her to be married. He said he would soon introduce her to her husband. She ran away and wrote a letter to the prosecutor reporting the threatened forced marriage and asking for help to protect her younger sisters. She also reported that they had all been *cut* and that the exciser was a friend of her mother's. There was a huge investigation all over Paris and the vicinity. The trial took 15 days.

I had a graphic excision film (produced by the Inter African Committee) played in court so that the jury could see what excision really was and understand what was at stake. There was a battle with the defence lawyers who did not want the film to be shown. But the judge allowed it because, after all, it was what we were talking about.

Mariatou and other victims testified. Some said they could not condemn their mothers because they only did what they knew as their custom. But Mariatou who had begged her mother to spare her younger sister, said her mother was aware what she was doing was hurting children. Her mother was sentenced to two years in prison. The prosecutor asked for 7 years in prison for the exciser but she was given 8 because I pushed for a harsher sentence. The other parents were each given 5 years suspended sentence.

LM: Your argument was that excision was a crime of mutilation like any other. Why then did the parents get mostly suspended sentences in nearly all the cases?

LWC: Because of the cultural aspect. The mothers would pretend to be ignorant of the law, even though the doctors testified that they had been warned. But in the end it is the jurors who had the final say and they didn't want to send the parents to prison. But a suspended sentence meant that if the parents did it again they would go straight to prison.

LM: Is there a requirement for girls under the age of six to have their genitals examined?

LWC: It's not exactly a requirement. The rule in France has always been that children under the age of 6 must be taken for medical checks and this is noted in their red book. So we asked the doctors that while they're doing these medical checks they also check the genitals in the presence of the mother. And while they do so they explain the law and that the genitals must stay intact.

It is a good practice because it dissuades the mothers who know the doctor will check and report them to the police if they cut their daughters. And it's not just focussed on excision, it can help detect other forms of violence against children, such as rape.

In 2011 I had a heated discussion with a female British politician (Lynne Featherson). I was talking about these genital checks. She said vehemently that she would never allow a doctor to examine the private parts of her daughter. She wouldn't even conceive that it is a medical act in order to protect the child. But we cannot be lenient because it's not fair on the children, they're the victims not the mothers.

LM: Was it difficult to convince the doctors to do the checks?

LWC: Once it is in their mind that it is a normal check like checking the ears or tummy then they do it. They know it's the best way to protect children and to inform the mothers that excision is forbidden. Some may say, 'they will think I'm racist so I prefer not to check'. But a child is a child whatever its colour and a mother is a mother.

Some mothers became crafty and would wait to have the excision done in their home country after the girl turned 6 and come back when she has healed. So then we had another problem to deal with.

Once, a woman had gone to the PMI and bragged that she was going to have the excision done back home. The doctor called me and said they had a child in danger. I had met the head of the women's health department in Mauritania at an FGM conference, and she had told me that if I ever had a problem to contact her. I informed her when the mother and the child were due to arrive at the Nouakchott airport. When they landed, a state official escorted them to the village and did not leave the child until it was time for them to return to France.

A meeting was held in the village and the outcome was: this little girl comes from France and she will return to France, so the village decided the child should remain intact. The African mothers in France heard what happened. They said, 'this mother was in her own country and the child has not been cut... it means if we return to our own country we can avoid the practice too'.

LM: Often authorities in the UK handover the responsibility for FGM prevention to the community leaders out of fear of being called racist. Does this strategy work?

LWC: It is the worst mistake they could make. I have always said that "community leaders" hold their positions and power because they respect tradition; you can't ask them to go against the tradition and inform the community that the tradition is not good. The authorities need to get involved themselves.

LM: Do you think people truly understand what FGM does to a woman?

LWC: A Somali activist (Leyla Hussein) made a film in which she moulded the private parts of a girl in clay so as to demonstrate excision to young boys who were arguing that it couldn't be that bad 'if our parents allow it on our sisters'. In the film she shows the moulded clay to the boys, gets hold of pruning clippers and violently cuts the sexual parts made of clay, explaining that 'this

is what is being done to your sisters'. Hers is one of the best films because it shows the cruelty of the act. If you don't see the act itself you can't measure the extent of damage and suffering.

LM: Do you get contacted by the girls (now women) you helped protect?

LWC: Yes. A year and a half ago a woman contacted me wanting to know if her parents had been tried. I checked and found the file. She read the file and felt completely disheartened but later she called and said, 'my youngest sister thanks you. Because of the trial she was saved'. And many have said the same thing over the years.

It is also very touching and inspiring to hear from the women who have had the surgery to reconstruct their clitoris. Dr Pierre Foldes is the French surgeon who invented the technique to reconstruct the clitoris. I have seen it done and it is done very precisely and delicately. It completely changes their lives. After they have healed the women speak about their renaissance; the joy of discovering their sexuality. It is wonderful to hear.

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