State-Corporate Facilitated Harms of the Pharmaceutical Industry: A Gendered Perspective

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Source: *Justice, Power and Resistance* Volume 3, Number 1 (March, 2019) pp. 89-114.

Published by EG Press Limited on behalf of the European Group for the Study of Deviancy and Social Control electronically July 2020

URL: http://www.egpress.org/papers/state-corporate-facilitated-harms-pharmaceutical-industry-gendered-perspective

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State-Corporate Facilitated Harms of the Pharmaceutical Industry: A Gendered Perspective

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Abstract

The pharmaceutical industry has long been recognised by criminologists as causing social harms towards individuals and groups, by engaging in unethical and illegal business practices in the pathological pursuit of profit (Braithwaite, 1984/2014; Bakan, 2005). This article argues that the neoliberal state is complicit and contributes to pharmaceutical harms due to its reluctance to effectively prohibit and sanction these (Tombs and Whyte, 2015). Neoliberal national healthcare politics and policies have also created rationale and opportunities for private profit creation by the pharmaceutical industry, and resultant social harms (Harvey, 2005; Dorling, 2014). Using a zemiological approach, this article specifically examines why women as healthcare recipients are disproportionately affected by pharmaceutical harms (Szockyi and Fox, 1996). It argues that women who experience social harms caused by the pharmaceutical industry are perceived primarily in relation to their reproductive and sexualised bodies, resulting in devaluation of their health and obscuring of state-corporate harms caused.

Key words*:* Gender, Neoliberalism, Pharmaceutical Industry, Profit, State-Facilitated Corporate Harm

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Introduction

The pharmaceutical industry is a known perpetrator of mass social harms on a global scale, which alongside their corporate profits are on the rise (Braithwaite, 1984/2014; Clinard and Yeager, 2006; Goldacre, 2013; Dukes et al, 2014). Pharmaceutical harms are also enabled by neoliberal states through problematic legislative frameworks which regulate rather than prohibit harms, prioritising corporate financial health rather than that of its citizens (Harvey, 2005; Dorling, 2014; Tombs and Whyte, 2015). Pharmaceutical harms are also justified by corporations and states through public discourses which deploy utilitarian arguments that any 'collateral' harms caused are in 'the common good' to enable medical or societal advances (Lee and Kohler, 2010; Rawlinson and Yadavendu, 2015). Everyone does not experience these harms equally however, as individuals and groups are affected differently by these dependent upon their societal position (Slapper and Tombs, 1999; Croall, 2008). Women as a specific group are argued to be disproportionately affected by pharmaceutical harms due to their (presumed) reproductive abilities (Claybrook, 1996; Finley, 1996). This assumption as Barton notes, is closely tied to: 'The image of the 'normal' woman…based around an idealised concept of femininity, which in turn is constructed around dominant discourses of domesticity, motherhood, sexuality and pathology' (1996:1). Deviation from these idealised norms of femininity which define acceptable and unacceptable female behaviour have been used throughout history to regulate women through the deployment of diverse control strategies including the criminal justice system, to dismiss their experiences of harms caused to them (Barton, 1996:1). These dominant discourses about women can be seen in relation to women's experiences of pharmaceutical harms, enabled by a complicit state.

This article analyses how women as healthcare recipients are disproportionately affected by harms perpetrated by the pharmaceutical industry aided by a complicit neoliberal state, utilising a Foucauldian feminist and zemiological analysis. This approach is useful in explaining how women are governed across multiple social sites in relation to their health. Relationships between women, the pharmaceutical industry and the state for example, are shaped by wider social processes where social controls are exercised upon women, such as norms and ideals of 'appropriate femininity' which they are expected to conform to (Foucault, 1980; Sawicki, 1991; Madriz, 1997; Hillyard and Tombs, 2004). Using examples from this under-researched area, this article argues that women's (presumed) reproductive abilities make them particularly vulnerable to pharmaceutical harms (Claybrook, 1996; Finley, 1996; Nippert et al, 2002; Tombs, 2016). It presents a detailed case

study of the vaginal mesh 'scandal' due to the lack of zemiological and criminological, rather than medicalised debates surrounding this.[2]

A documentary analysis of sources including public health documents, news media articles, books and journal articles have been utilised in this research (Mason, 1996:71-9). Sources were found via an extensive on-line literature search involving key words such as 'pharmaceutical harm', 'women', 'vaginal mesh' and 'breast implants'. Due to the dearth of zemiological and criminological knowledge around pharmaceutical harms to women particularly those involving vaginal mesh, the research aimed to gather existing academic, public, medical and state-corporate knowledge in this area (cf. Peppin, 1995; Claybrook, 1996; Finley, 1996; Croall, 2008). It also aimed to challenge 'conventional' scientific rather than zemiological or criminological discourses about pharmaceutical harms to women (Foucault, 1980:81-2; Mason, 1996:3). The research examined how effective state-corporate processes ostensibly designed to prevent pharmaceutical harms to women, and how women's experiences of these harms were discussed. Where quotes from, or information about women harmed by pharmaceutical products are used, these are from publicly available sources rather than primary research, thus minimising potential ethical issues (Mason, 1996:78).

The article makes two main points in relation to gendered pharmaceutical harms. Firstly, it argues that largely preventable and foreseeable gendered pharmaceutical harms perpetrated by pharmaceutical companies and an enabling state, are justified through a utilitarian calculus which prioritises medical and social advancements above 'collateral' harms to women. Secondly, it argues that government neoliberal discourses in relation to health are worsening the obfuscation of gendered pharmaceutical harms and state-corporate accountability for these. It then concludes after a discussion of the possibilities for resistance to pharmaceutical harms to women. The aim of this article is not to repeat notable existing discussions in relation to the harmful corporation *per se* (Braithwaite, 1984/2014; Dukes et al, 2014; Tombs and Whyte, 2015; Tombs, 2016). Rather, it aims to bring a detailed examination of gendered pharmaceutical harms (again) to the forefront of critical criminology's attention (Mintz, 1985; Claybrook, 1996; Finley, 1996; Croall, 2008).

[2] A term used to obscure the impact and nature of harms caused, and to dismiss the legitimate grievances of victims (Tombs and Whyte, 2007:71).

Pharmaceutical Harms under Neoliberalism

The pharmaceutical industry has long been recognised as a perpetrator of mass social harms in a range of diverse ways by criminology (Braithwaite, 1984/2014). Criminologists including corporate and white-collar crime scholars have given comparatively little attention however, to pharmaceutical harms in comparison to other forms of social harm (cf. Braithwaite, 1984/2014; Croall, 2008; Dukes et al, 2014; Rawlinson and Yadavendu, 2015; Tombs and Whyte, 2015; Rawlinson, 2017). A notable exception to this is Braithwaite's seminal study (1984/2014) into corporate crime within the pharmaceutical industry, which found extensive and global wrong-doing within companies resulting in social harms towards consumers. He found that pharmaceutical companies engaged in illegal, unethical and harmful behaviours such as bribing government officials, use of dangerous manufacturing processes, negligence and fraud in drug safety testing. Despite this evidence, there is still a widespread public expectation that the pharmaceutical industry will research, develop and produce drugs for 'the common good' to *improve* rather than *harm* public health outcomes. Using this utilitarian justification, it is also presumed that 'collateral' harm is inevitable to enable medical and social advances (Lee and Kohler, 2010). This rationale however is problematic and has been used throughout history, to justify mass harms and atrocities such as the Holocaust by Hitler's Nazi Germany during World War Two, Thalidomide and pharmaceutical trials on those living in the Global South to benefit the health of individuals in Western countries (Rawlinson and Yadavendu, 2015).[3]

The presence of a 'state-pharma nexus' (Rawlinson, 2017) whereby states enable the harm causing behaviours of the pharmaceutical industry is also clear. The pharmaceutical industry is known for example, to breach laws ostensibly meant to prevent social harms (Braithwaite, 1984/2014; Clinard and Yeager, 2006:xxi). However, state legislative frameworks which apply to corporate wrong-doing are often based on a misplaced confidence in the criminal law as an impartial adjudicator, rather than a state instrument of power, reflecting its own capitalist interests which is used to further these. Pharmaceutical companies moreover maximise their profits and avoid national legislative frameworks by moving their operations to poorer countries with less legislative safeguards for workers, consumers and the natural environment, which nation states use to attract corporations there (Tombs and Whyte, 2007; Tombs and Whyte, 2015; Rawlinson and Yadavendu, 2015). State-corporate pharmaceutical harms therefore: '…often emerge from

[3] Thalidomide is discussed later in this article.

intersections of economic and political power' and are perpetrated in the pursuit of mutual economic and political interests by states and pharmaceutical corporations (Michalowski and Kramer, 2006:3). State political decisions therefore can result in financial and economic social harm perpetration due to mis-appropriation of public funds by governments and private corporations including the pharmaceutical industry via: '…increased prices for goods and services through cartelisation and price-fixing, and redistribution of wealth and income from the poorer to the richer through regressive taxation and welfare policies' (Hillyard and Tombs, 2004:19).

Neoliberalism, Health and Harms

Neoliberalism continues to exert a considerable influence upon state political policies, which has created almost perfect conditions for pharmaceutical profit maximisation and increased harm perpetration. As a political ideology, neoliberalism encourages the private owners of capital and production to create profit through a hegemonic project which concentrates power and wealth within elite groups to the detriment of other social groups (Saad-Filho and Johnston, 2004:1). In relation to health, the neoliberal agenda continues to worsen and legitimate rising inequalities and to cause social harms, through beliefs in macroeconomic policies and market reliance to solve wider structural inequalities (Harvey, 2005; Stuckler and Basu, 2013; Dorling, 2014). Individuals and groups who already find themselves marginalised within society because of class, 'race', age, gender, sexuality and (dis)ability, are disproportionately affected and harmed by neoliberal policies which prioritise corporate fiscal health over citizens' health (Connell, 2014; Bell and Scott, 2016). Neoliberalism's impact upon women includes worsening the impact of existing structures in society which position them in a subordinate socio-economic position in relation to men; structures which are essential to the accumulation of capital (Braedley and Luxton, 2014).

In the United Kingdom (UK), the public healthcare budget for the National Health Service (NHS) was ostensibly protected from austerity measures but had significant spending cuts due to a lack of inflationary increases which were obscured from public debate at the time (HM Treasury, 2010). These have resulted in patient fatalities and harms in UK hospitals and in the wider community (Francis, 2013; Dorling, 2014). A mistaken neoliberal assumption that markets, competition and profits will always be preferable to state interventions however, has encouraged government policies and subsidies enabling the growth of private and corporate profit seeking parts of the healthcare sector where: '…private profiteers are replacing dedicated doctors.' (Stuckler and Basu, 2013:106). This has directly led to the demise of

public healthcare provision which has become a: '…residual system, the second-best choice for those who can't afford the real thing.' (Connell, 2014). Government neoliberal agendas also emphasise individual responsibility for, rather than a right to health, to blame individuals for their poor health and to justify reduced public spending on healthcare whilst private corporate profits benefit from the provision of services and goods which 'fill the gap' (Hillyard and Tombs, 2004; Polzer and Power, 2016).

A neoliberal political economy of health which concerns political power over resource allocation, has also helped the pharmaceutical industry to exert a '…deeply concerning' power and political influence over healthcare, through doctors and governments (Mooney, 2012:7). The UK House of Commons Health Committee states: 'The industry is hugely influential, affecting every aspect of the medical world, including prescribers, patients, academics, the media, and even the institutions designed to regulate it. Its influence in Parliament is extensive' (2005:8). The pharmaceutical industry therefore, is unlikely to be held accountable for harm perpetration by a complicit state. The pharmaceutical industry has also encouraged 'pharmamedicalisation'; an unhealthy reliance and over-use of drugs in health conceptualisation and administration (Rawlinson, 2017:95). This leads to a perception that pharmaceutical products are essential for the health and wellbeing of individuals and groups within society, whilst exposing them to increased risks of drug-related illnesses and financial harms through mis-use of personal and public funds. Aided by a neoliberal emphasis on privatisation and a free economic market, pharmaceutical companies also take advantage of their privileged position in healthcare to engage in profiteering through charging the NHS excessive drug prices due to weak public-sector bargaining mechanisms (Hillyard and Tombs, 2004; House of Commons Health Committee, 2005:8). The pharmaceutical industry also receives *public subsidies* to encourage innovative drug development for *private profit*, which is more expensive and less profitable than developing similar 'me-too' drugs based on those which already exist (Goldacre, 2013).

The state is also responsible for enabling social harms caused by the pharmaceutical industry through its regulation rather than prohibition of pharmaceutical harms, further encouraged by a neoliberal agenda of deregulation which prioritises private profit over public health and safety (Tombs and Whyte, 2007; Tombs and Whyte, 2015). Within the UK, regulators such as The National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare Products Regulatory Agency (MHRA) increasingly perceive pharmaceutical companies as their customers rather than patients leading to the establishment of: '...a 'neo-liberal corporatist partnership' with

the industry (Davis and Abraham, 2012:493).[4] This results in the pharmaceutical industry dictating strict targets for the speed of drug review and marketing approval in exchange for extensive secrecy over regulatory decision-making and industry fees, raising concerns about patient safety and drug efficacy. The pharmaceutical industry has also succeeded in shortening costly drug trials resulting in 'surrogate outcomes', which may give misleading results about drug efficacy and effectiveness for longer term patient use. Pharmaceutical companies furthermore, often engage in 'ghost-writing' of academic and non-academic journal articles known to influence public policy and public opinion, which they sponsor to present more positive outcomes for the industry (Mooney, 2012; Goldacre, 2013).

Gendered Pharmaceutical Harms to Women

A dearth of criminological attention has been paid to pharmaceutical harms specifically in relation to women (see for exceptions Peppin, 1995; Claybrook, 1996; Finley, 1996; Croall, 2008). This is arguably due to a general 'gender blindness' within criminology in relation to all forms of corporate crime (Croall, 2008:137). Generally, the chances of women experiencing certain types of corporate social harm can be affected by the work they do, job-related restrictions due to exclusions applying to women based on reproductive or other sex-based hazards or discrimination, the separation of home work from paid labour, and societal cultural norms and standards in relation to masculinity and femininity (Simpson and Elis, 1996:33-34). This is different from arguing that women experience corporate social harms more than men as a societal group. Rather, women are more vulnerable to experiencing certain types of pharmaceutical harms due to societal and cultural factors including (men's) desire to change or alter women's bodies (Croall, 2008:137). Women are specifically vulnerable to the risk of 'gender-specific' or gendered pharmaceutical harms because of social and cultural norms about their (presumed) reproductive abilities in relation to childbirth, pregnancy, ovulation and menstruation, which men cannot directly experience. Throughout history, women's bodies have been medicalised, subjected to intrusive forms of surveillance and thus social control, and perceived as more

[4] NICE oversee the commissioning and approval of *all* new health technologies used in NHS clinical care, including pharmaceutical drugs. They assess and make recommendations about the clinical and cost-effectiveness of all new health technologies and produce clinical practice use guidelines (2018). MHRA is the UK government body which regulates medicines and investigates incidents where these have caused harm. In Europe, the European Medicines Agency (EMA) is also responsible for regulating the safety and efficacy of pharmaceuticals (Department of Health and Medicines and Healthcare Products Regulatory Agency, 2016).

liable to ill health than the male body. They have also been perceived as a site of contamination due to associations with fluids and leakage tied to their assumed reproductive capacities (Barton, 1996; Bridgeman and Millns, 1998). Consequently, women are more likely to experience the medical profession than men, to undergo more potentially harmful medical and surgical interventions, and are therefore more vulnerable to pharmaceutical harms (Petersen and Lupton, 1996; Schlichthorst et al, 2016:1028).

In relation to pharmaceutical harms to women, Foucault's concept of biopower allows a critical examination of how gendered medicalised discourses are inextricably linked to state power. Conceptually, biopower captures all the forms which power takes towards individuals within society which subject them to sexual and biological norms. Biopower relates to the administration of life itself and includes two connected forms. The first of these Foucault termed '…an *anatomo-politics of the human body*' and concentrates on the disciplining of the individual body as a machine (1990:139). It is focused on optimising the body's usefulness and its docility, and its incorporation into efficient economic systems through processes of power. Part of this process are medical norms which define individuals in relation to their health and categorise it as 'unhealthy' 'ill' or 'abnormal'. Arguably added to these is 'incomplete', in recognition of the gendered and sexualised discourses which surround the neoliberal female body of health. Once an individual's body is categorised; a process which invariably relates to social exclusion or marginalisation, a health industry exists to both continually service and remedy this 'inadequacy' or 'lack', such as the diet, cosmetic surgery, or the 'mothering' industry. The politics and economics of corporations including those of the pharmaceutical industry are closely connected to these. Due to the influence of neoliberalist politics and economics upon the state which emphasises the primacy of corporate profit making in a free market, pharmaceutical companies are then optimally placed within this not just to create mass profits, but also mass social harms (Harvey, 2005). Neoliberalist influences upon the state mean that historically established forms of corporate regulation and criminal sanctions, however flawed, become less effective through a loosening of 'corporate red tape' to enable profit making (Tombs and Whyte, 2015).

The second form of biopower Foucault termed '…*a bio-politics of the population*', focused on social groups in relation to the human body, its ability for reproduction and the 'mechanics of life' such as births, mortality, health levels, life expectancy and longevity (1990:139). Significantly, Foucault was concerned with examining *all* the conditions that cause these to vary. This form of biopower of the population is concerned with states or governments harnessing human bodies, both as a resource to be used and protected, which

are subjected to forms of surveillance aiming to improve them. Public health campaigns about sexual health, breast feeding, exercise or healthy eating, and dictatorial and/or punitive societal discourses around those who do not meet these norms, are all forms of this type of biopower. Foucault examined how these forms of regulatory control were affected on and through individuals in society. Significantly, biopower has been an essential element in the development of capitalism and thus the dominance of the corporation as it: '…would not have been possible without the controlled insertion of bodies into the machinery of production to economic processes.' (Foucault, 1990:141). It also needed these bodies to be docile and to have methods of power to make them so. Following this, a bio-politics of the population as a form of biopower, must have also been '…indispensable to patriarchal power as it provided instruments for the insertion of women's bodies into the machinery of reproduction' (Sawicki, 1991:68). Patriarchy defined in Foucauldian terms is: '…a global effect of domination made possible by a myriad of power relations at the microlevel of society.' which acknowledges that there is no general theory which can encapsulate this, nor one location or place of resistance (Sawicki, 1991:59). It recognises that certain groups of men, for example, those who are gay or working-class, can also be subject to patriarchy. Feminist struggles for women's control of their own bodies have been part of the history of biopower (Sawicki, 1991:68).

Neoliberalism which is dependent upon capitalism and patriarchy, influences how women who experience pharmaceutical harms are perceived and their agency relating to their health. The aforementioned 'responsibilised individual' which neoliberalism advocates, is based upon a comparatively socially and economically advantaged *male* subject encouraged to rely on their own resources to solve health issues and to make 'free choices', often through the neoliberal co-option of feminist discourses of empowerment. Although under neoliberalism women may feel empowered and able to exercise 'choice' in relation to healthcare, they *must* make the 'right' choices as consumers of products rather than recipients of care (Scharff, 2016). The neoliberal rhetoric of 'choice' is also problematic as it ignores health inequalities, cultural and social idealised norms of femininity which continue to devalue, oppress and subordinate women because of their (presumed) reproductive abilities. Women's citizenship is also dependent upon *their* responsibility not to become ill due to *their* negligence nor to become a burden on their family or the state, through engaging in state and self-surveillance and bodily regulation activities (Petersen and Lupton, 1996:79-80; Bell and Scott, 2016). Neoliberal emphasis upon women's individual responsibility for their health means that when they experience pharmaceutical harms in relation to their (presumed) reproductive abilities, these are justified through a neoliberal lens which

emphasises a teleological, linear and egalitarian account of medical and social development, thereby undoing the need for social movements such as feminism to effect change. These gendered harms are then obscured, dismissed and trivialised, with *women* blamed for these (Claybrook, 1996; Finley, 1996; Foucault, 2002; Polzer and Power, 2016; Scharff, 2016).

A further impact of this is that when women have tried to legally pursue companies to gain compensation for pharmaceutical harms caused to them, their reproductive injuries have not been placed at a high value due to societal and cultural norms which devalue women's bodies (Finley, 1996). Reproductive harms are also devalued as they are not easy to quantify, are perceived in emotional rather than physical or economic terms and are minimized as too subjective. This is closely tied to the construction of women as 'emotional' and 'hysterical'; terms used throughout history to dismiss their experiences and complaints about harms caused to them (Worrall, 1990; Barton, 1996:11). Therefore, although used as a societal means to control women: 'While supposedly a priceless asset in cultural terms, economically speaking, a woman's reproductive capacity is virtually worthless.' (Finley, 1996:75). Gendered pharmaceutical harms to women based upon their (presumed) reproductive abilities are not therefore a rare 'aberration', rather they are a common occurrence and risk in women's lives, as shown by the following examples.

A Brief History of Gendered Pharma-Harms

In the 1930's, diethylstilbestrol or DES was a synthetic estrogen used to treat pregnant women for morning sickness and to ensure that their babies were born healthy. Despite tests on animals which proved the potential harms of using the drug, it continued to be marketed and sold and its use resulted in women suffering miscarriages, infertility and babies being born 'deformed'. In America, the Federal Drug Administration (FDA); the United States of America's (USA) drug regulatory body, did not allow pharmaceutical companies to use DES for unapproved uses such as in pregnant women. Pharmaceutical representatives however, encouraged doctors to use the drug on pregnant women and donated supplies of the drug to enable this. Finley argues:

> The exclusive focus of the pharmaceutical industry on what DES might do *for* women, instead of also on what it might do *to* women, demonstrates their greater concern for controlling the female reproductive system for profit than for the ultimate health and safety of women. (Finley, 1996:63-64)

Women also experienced 'victim-blaming' based on idealised norms of femininity when they brought legal cases against pharmaceutical companies for harms it had caused them. Women were accused of causing these harms through their lifestyle and sexual behaviour such as having more than one sexual partner, and/or a sexually transmitted disease which had caused their infertility (Barton, 1996:1). In the 1960's, American companies the Dalkon Corporation and then later A.H. Robins, manufactured the Dalkon Shield; an intra-uterine contraceptive device. It was marketed and sold despite corporate knowledge of issues with the material used for the device's filament strings, which were dangerous to women as infection could be carried directly into the womb through the wicking of the strings. Thousands of women who had a Dalkon Shield device inserted suffered miscarriages, infertility, infections and unwanted pregnancies. Pharmaceutical companies again tried to evade responsibility through bankruptcy and engaged in 'victim-blaming' utilising idealised norms of femininity to interrogate women with degrading questions about their previous sexual partners, lifestyle and 'toilet habits' (Mintz, 1985; Finley, 1996:87).

The thalidomide 'scandal' erupted in 1962 in America and involved a sedative drug prescribed to women for morning sickness which caused babies to be grossly deformed. Pharmaceutical manufacturers ignored known dangers of the drug and publicly denied any link to harm. The 'scandal' resulted in a legal change which meant that a drug's effectiveness needed to be proved before it could be approved for sale by the FDA in the USA. Thalidomide continues to cause harms in the lives of those women and their children (Nippert et al, 2002). Moreover in 2010, 400,000 female patients in 55 different countries were affected by Poly Implant Prothese (PIP) breast implants manufactured by French company Poly Implants Prosthese Prothese (Oulharj et al, 2014:304). PIP breast implants were withdrawn from UK markets after it was discovered that the implants had been fraudulently manufactured using cheap industrial rather than medical grade silicone which had saved the company 1.2 million euros. Jean-Claude Mas; the company's founder, fraudulently misled the French authorities about the implants' safety and efficacy through ignoring safety tests, whilst exposing women to ill health. A French criminal court case convicted him of aggravated fraud and sentenced him to four years imprisonment with a €75,000 fine (£63,000) involving 7,113 women from 71 countries as plaintiffs. Four company executives were also imprisoned (Benkimoun, 2013).

In common with other gendered pharmaceutical harms, the PIP 'scandal' had striking similarities to 1991 when the Dow Corning Corporation in America was found liable for fraud, malice and oppression in the manufacture and sale of defective and unsafe silicone gel breast implants. The claimant Mariann

Hopkins was awarded damages for suffering from an immune disorder after she was exposed to silicone gel from breast implants which were inserted after a double mastectomy. The court found that Dow Corning had acted knowingly with disregard for her safety and rights, exposing her to cruel and unjust hardship. Far from being an isolated incident, earlier in 1984 Dow Corning had been found similarly liable for 'corporate malice' in a product liability lawsuit for silicone breast implants against Maria Stern. The case was the first of its kind to be tried successfully and Stern was awarded $1.5 million in punitive damages. Dow Corning knew in 1972; twenty-one years before Mariann Hopkins brought her case to trial that silicone could move to other parts of the body including the immune system. Many more women harmed by all these cases of pharmaceutical harms never and understandably, undertook the arduous route of legal action (Claybrook, 1996).

The gendered pharmaceutical harms caused to women by drugs given during pregnancy, contraceptive devices, and faulty breast implants are however not isolated incidents. They are, as the following discussion about vaginal mesh implants will show, characteristic of corporate pharmaceutical deviance throughout history repeating itself. They demonstrate women's bodies continuing to be harmed due to cultural factors and attitudes, which focus more on the benefits of medical 'progress' for pharmaceutical companies enabled by a complicit state, rather than the overwhelming dangers of pharmaceuticals to women's health. Although women have *generally* gained reproductive 'freedom' and 'choice' through medical advances in this area, these have not been without significant harms caused to women as a social group. It has also produced significant benefits for men as a social group in relation to reproductive responsibility, which women are still largely responsible for. As the following discussion of the vaginal mesh 'scandal' will show, these harms continue in the present day (Finley, 1996:92). The persistence of these gendered harms may also show an acceleration of pharmaceutical corporate harms due to the inability of pharmaceutical companies, and corporations generally, to *not cause harm* to women through engaging in unethical and illegal business practices in the pathological pursuit of profit (Braithwaite, 1984/2014; Bakan, 2005; Dukes et al, 2014; Tombs and Whyte, 2015).

The vaginal mesh implant 'scandal'

In the UK in 2017, NICE issued clinical guidance on the use of mesh in transvaginal repair of anterior or posterior vaginal wall prolapse in women due to childbirth or to treat urinary incontinence. NICE recommended that transvaginal mesh repair should only be used in the context of research, as

there was evidence of serious and well-recognised safety concerns about their use and inadequate evidence about their long-term effectiveness (2017:2). Based on existing clinical studies NICE estimated that twelve per cent of women who had vaginal mesh experienced complications after two years of implantation, with nine per cent needing removal of it. They noted that when complications occurred in women that '…these can be serious and have life changing consequences' (2017:8). In comparison, only one per cent of women who had a biological graft made from their own or sterilised cadaveric tissues implanted experienced complications (NICE, 2017:5; Campbell, 2018). Transvaginal repair with mesh involves removing some tissue which has been stretched and tightening the underlying tissue. Mesh is used to support the repair and the operation is usually done under general anaesthetic (NICE, 2017:3). The mesh is usually made from polypropylene plastic as it can withstand an autoclave and be used in the manufacture of medical devices (Campbell, 2018). Mesh devices differ in pore size and fibre configuration, can include a non-absorbable coat covered with a thin layer of collagen and their size can vary. Around 10,000 women a year in the UK have vaginal mesh implanted, and from 2006 to 2017, over 130,000 women were implanted with vaginal mesh, and 6,000 women underwent procedures to remove or partially remove their mesh implants (Marsden, 2017a; 2017b). In America nearly 790,000 vaginal mesh devices were sold, with two million worldwide (Dyer, 2016).

The impact on women of vaginal mesh implants

Serious complications however, can occur with vaginal mesh implants as polypropylene mesh can shrink by up to half four weeks after implantation (Henegan et al, 2017). Women who were fitted with a vaginal mesh repair therefore experienced a range of physical harms from infection, urinary retention, dyspareunia or other pain, alongside other mesh complications (Glazener et al, 2017). Dawn Martin aged 55 who had vaginal mesh implanted to treat incontinence after childbirth, experienced chronic pain. She was also admitted to intensive care in hospital after having a severe reaction to the painkiller used to treat her chronic pain. When she *eventually* got doctors to agree to remove her mesh, reflecting many women's experiences of state-corporate harms towards them being disbelieved or being labelled as 'hysterical', they found it had shrunk more than expected and was cutting through her urethra into her bladder (Worrall, 1990; Barton, 1996). She *still* suffers from health issues saying: 'I don't feel attractive anymore. It's aged me by 20 years. I feel like a completely different person' (quoted in Sanghani,

2017). June Smith, aged 67, also experienced chronic pain due to the implant and felt she had broken glass inside her. She said: 'I told my husband I couldn't continue with the pain and wanted to kill myself' (quoted in Sanghani, 2017). Chrissy Brajcic from Ontario in Canada was 42 years old when she died of complications after having vaginal mesh fitted. She was left bedridden and in pain after her procedure which was to treat minor incontinence. She experienced recurrent infections because of the operation and became resistant to the antibiotics used to treat her. She then later contracted sepsis and died of organ failure (Marsden, 2017b).

A common issue of the women who received vaginal mesh implants and similar to other pharmaceutical harms, was the absence of their informed consent due to their lack of knowledge about the risks and benefits of the treatment. Ethicon, the Johnson and Johnson division which marketed vaginal mesh, did not inform women nor doctors that it had mainly been tested upon sheep and in a short-term medical trial lasting a few days on only thirty-one women (Marsden, 2017b).[5] The trial was unlikely to reflect the long term harmful impact to women of implanting vaginal mesh in them as due to biological incompatibility, non-human trials are not comparable to those on humans. Human medical trials are therefore essential to assess the potential long-term impact and harms of any medical device but as argued earlier, these are often costly and avoided by pharmaceutical companies or are often shortened with 'surrogate end points', which mean that the harmful long-term effects of drugs are masked until consumers use them (Goldacre, 2013; Henegan et al, 2017). It has also been alleged that Ethicon did not fully inform doctors of the risks of using vaginal mesh in women and hid its knowledge about potential adverse effects including those which were permanent. This resulted in lawsuits against Johnson and Johnson in multiple jurisdictions (Dyer, 2016; Richards, 2017).

The failure of regulatory frameworks

Significantly, the governance of medical devices by state regulatory bodies which approved the marketing of synthetic vaginal mesh products in the USA and Europe was problematic (Henegan et al, 2017). This reflects wider concerns raised by criminologists in relation to the (in)effectiveness and (in)ability of state regulatory structures to hold corporations accountable for their harmful actions (Braithwaite, 1984/2014; Dukes et al, 2014; Tombs and

[5] In *Schloendorff v Society of New York Hospital* 105 NE 92 (NY, 1914) Judge Cardozo defined informed consent as: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without the patient's consent commits an assault.' (Laurie et al, 2016:68).

Whyte, 2015). In common with other pharmaceutical harms 'scandals' involving women previously discussed, the potential harms of vaginal mesh implants were known about or alternatively ignored for decades by their manufacturers before they were marketed, as they were not tested on a meaningful sample of women during trials (Marsden, 2017b). Significantly, the mass pharmaceutical harms caused to women by vaginal mesh implants had also been known in the medical world for some time before the 'scandal' erupted in 2017. In the UK for example, NICE knew in 2005 that there was a need for vaginal mesh studies with longer term follow up and stated that women should be informed about the lack of any long-term data about health outcomes (Henegan et al, 2017).

In the European Union (EU), manufacturers of medical devices need to apply to any 'notified body' in an EU country to gain approval for its marketing across any country within the EU. Within the UK for example, the MHRA authorise 'notifiable bodies' which assess whether manufacturers and their medical devices meet safety and efficacy requirements set out in relevant EU legislation in relation to a product (UK Government, 2017). Once approved under this process, manufacturers are issued with a certificate and allowed to use the CE 'quality' mark which signifies that it meets EU health, safety and environmental standards (UK Government, 2012). NICE work closely with the MHRA to ensure that information about a medicine or treatment's safety and efficacy is shared appropriately to enable effective decision-making about it (Department of Health and Medicines and Healthcare Products Regulatory Agency, 2016). This regulatory process ostensibly meant to ensure the safety and efficacy of a medicine or treatment however, failed in relation to the approval of vaginal mesh implants. This is perhaps unsurprising as regulatory systems have been criticised for being inadequate in ensuring patient safety, as their decision to approve a drug or medical treatment is based upon insufficient evidence about its safety and efficacy. Instead it relies on its 'presumed' similarity to a previously approved product, which could have gained approval over a decade before (Henegan et al, 2017:5-7).

Despite strong objections by the industry themselves, pharmaceutical products and devices are legally regulated under the Consumer Protection Act 1987.[6] This creates strict liability so that consumers only need to prove a causal act without any form of mens rea or 'guilty mind' such as intent, negligence or recklessness, by a company. A degree of safety which 'persons generally are entitled to expect' is applied to pharmaceutical products under section 3(1). Manufacturers however will not be liable for defects which they could not be

[6] European Union Council Directive 85/374/EEC on product liability. At the time of writing, these laws were in force in the UK.

expected to discover at the relevant time of manufacture due to the state of scientific and technical knowledge at the time under section 4(1)(e). This is problematic as for example, the investigating authority for the MHRA in the PIP breast implant 'scandal' discussed previously, concluded that lack of clinical data and poor record keeping by manufacturers resulted in inconclusive evidence as to the health and safety of the implants. The UK Department of Health's Report into PIP breast implants also agreed with this conclusion (Laurie et al, 2016:170-171). This in effect rewards corporations who intentionally, negligently or recklessly decide not to keep effective record to maximise profit margins and can be used to evade legal claims made against them.

In America, pharmaceutical products are regulated by the FDA, whose effectiveness as an independent regulatory and enforcement agency which ensures the safety and effectiveness of pharmaceutical products is questionable, as it receives its funding from pharmaceutical companies themselves (Dukes et al, 2014:170). Significantly in relation to vaginal mesh, the FDA first approved synthetic polypropylene mesh for use in hernia repair between 1985 and 1995, but significantly *no* vaginal mesh was approved. In 1996, Boston Scientific's ProteGen® mesh was the first approved specifically for use in vaginal prolapse procedures. Controversially however, it was approved under the FDA's 510(k) pre-marketing notification process which allows manufacturers to market a new product without considerable testing if it is thought to be substantially equivalent and at least as safe and effective as a legally marketed device, as it was based on pre-approved mesh for hernia repair. No further testing was therefore needed despite an absence of safety tests on the surgical use of mesh in women for vaginal prolapse (Campbell, 2018:51-52). FDA approval was given for a vaginal mesh product which was significantly different from the one initially approved due to a series of approvals which resulted in 'predicate creep': '…whereby the numerous changes result in a new device that is very different from the original predicate device.' (Henegan et al, 2017:1). State regulatory structures in both the UK and America specifically therefore did not prevent pharmaceutical harms to women which were *known* to both manufacturers and regulators, due to a neoliberal agenda which prioritises the profits of corporations in the mutual interests of the state (Michalowski and Kramer, 2006:3). The UK state specifically were also typically *reactive* rather than *proactive* about the corporate harms of vaginal mesh only after women raised social awareness of the issue through collective in addition to individual activism, and mass harms had already been caused.

Resisting Gendered Pharma-Harms

Resistance against pharmaceutical companies in relation to gendered harms is crucial in trying to tackle and dismantle harmful corporations and to replace them with less harmful alternatives (Tombs, 2016:207-210). Academic arguments can play a key role in highlighting state-corporate collusion, resultant harms and in effecting social change. More criminological attention is also clearly needed in relation to state-corporate harms towards women, including those committed by the pharmaceutical industry. Activism is however an essential form of resistance to state-corporate harms which can change the course of social events. Throughout history, feminist collective and individual activism has secured significant improvements to women's lives. Specifically, collective activism can be an effective 'antidote' to individualist and responsibilising neoliberal discourses deployed in relation to gendered (pharmaceutical) harms to women which depoliticise issues of social harm about women's health (Scharff, 2016:52-4). Collective activism is essential for women to be 'taken seriously' and for meaningful social change to occur through societal disapproval towards corporate harm perpetrators and complicit states (Oakley, 1993:18; Stanley and McCulloch, 2013:4). Activism is also essential to counter the prevailing view that the pharmaceutical industry works for 'the common good' in the interests of patients and their well-being, rather than its own corporate financial well-being (Goldacre, 2003; Lee and Kohler, 2010).

In relation to vaginal mesh implants for example, 'Sling the Mesh'; a UK campaign group set up by Kath Sansom for example, advocates on behalf of all women who have been affected by them (Sansom, 2018). It has been successful in raising national awareness of the harms caused by vaginal mesh implants including gaining the vocal support of UK Member of Parliament Owen Smith, which prompted UK government action to investigate and then prohibit their marketing (NICE, 2017; Matthews-King, 2018). Similarly, women harmed by the PIP breast implant 'scandal' mentioned previously, set up the PIP Action Campaign; a not-for-profit social networking campaign across Facebook, Twitter with a central website which is run by those directly affected by them (PIP Action Campaign, 2018). Amongst these social networks for example, a Facebook group called PIP Implants OPIC (Official PIP Implant Campaign) with over 1,000 members was set up by women with PIP breast implants. These have raised societal awareness of the pharmaceutical harms caused to women and have been a crucial site of both support and resistance

to their dangers, which were being ignored by governments (Roderick, 2017). The collective legal action taken on behalf of women harmed by PIP breast implants in France discussed earlier, further demonstrates the power of collective action against gendered pharmaceutical harms (Benkimoun, 2013). Although they resulted in a successful legal outcome for both women, the litigation against Dow Corning in America of Maria Stern and Mariann Hopkins in relation to harm caused by faulty breast implants, shows the difficulties for *individual* women to challenge harms caused by a *collectively* powerful pharmaceutical industry and complicit state, which relied on idealised norms of femininity regarding the *individual* sexual behaviour and lifestyle of women to engage in 'victim-blaming' thereby depoliticising gendered pharmaceutical harms to them (Finley, 1996:76).

Significantly, questions about *in whose interests* do utilitarian justifications in neoliberal discourses for medical and social advances such as 'the common good' operate, need to be raised as this 'progress' has often been made at the expense of women's health. To prevent the reoccurrence of the atrocities and harms of the past which were argued to be 'in the common good' and in the name of 'progress', the balance of social harms versus benefits to society needs to be subjected to careful *independent* scrutiny, rather than leaving this to the likely biased judgement of the pharmaceutical industry, or the neoliberal state due to its lack of interest both in preventing rather than regulating pharmaceutical harms, and the role of structural constraints (Tombs and Whyte, 2007; Rawlinson and Yadavendu, 2015). It is also crucial in undermining neoliberal gendered discourses which construct women as individual responsibilised subjects who are empowered to make 'good' decisions about their health through idealised norms of femininity, whilst ignoring the power and influence of a pharmaceutical industry enabled by a complicit state, upon women's experiences as consumers and patients (Barton, 1996:1).

Due to the dominance and power of the corporation in society enabled by a complicit neoliberal state, discourses of resistance which dispute corporate versions of social harm perpetration, are also often hidden, obscured, dismissed or at best somewhat listened to and marginalised. Therefore, empowering women so that they can speak out and 'strike back' against the abuses they have experienced is key (Oakley, 1993:18; Snider, 1996:256; Tombs and Whyte, 2015). Although the harms caused to women by vaginal mesh implants were acknowledged *eventually* for example, the neoliberal state and pharmaceutical corporate response to them is still inadequate (NICE, 2017). Many women with vaginal mesh implants have faced an uphill struggle to be both listened to and have these removed, rather than be labelled dismissively by doctors as 'hysterics' (Worrall, 1990; Barton, 1996:1; Sanghani,

2017). It is essential that women's experiences of gendered pharmaceutical harms are recognised as a form of 'subjugated knowledge'. According to Foucault these are: '…a whole set of knowledges that have been disqualified as inadequate to their task or insufficiently elaborated: naïve knowledges, located low down the hierarchy, beneath the required level of cognition or scientificity' (1980:81-82). These are low-ranking or disqualified knowledges from categories of individuals in society such as 'the ill person' and 'the psychiatric patient'. Foucault argues that criticism and resistance to these forms of power and knowledge is essential and can occur and speak truth to power through '…an insurrection of subjugated knowledges' which uncovers conflicts and struggles which have been obscured. Significantly according to Foucault, power and knowledge are not only oppressive but can also be used as forms of resistance and become liberatory (1980: 81-82). Subjugated knowledges such as the experiences of women harmed by pharmaceuticals including vaginal mesh implants, are a key form of resistance as they can both undermine neoliberal state-corporate harmful hegemonic discourses and practices, and contribute to a zemiological analysis of these.

Conclusion

This article has argued that despite receiving a limited amount of criminological attention due to the gender blindness of corporate crime studies, a critical examination of the gendered pharmaceutical harms caused to women by the pharmaceutical industry is vital (Croall, 2008). It has shown how the recent vaginal mesh implant 'scandal' discussed is just one example of a litany of gendered pharmaceutical harms, which continue to be everyday experiences in the lives of women globally (Mintz, 1985; Claybrook, 1996; Finley, 1996; Nippert et al, 2002). Women's (presumed) reproductive abilities have meant that throughout history, their bodies have been medicalised and subjected to surveillance, to control and subjugate them (Bridgeman and Millns, 1998). This has also meant that women have been more vulnerable to specific types of corporate harm and specifically pharmaceutical harms including in relation to menstruation, pregnancy, abortion, miscarriage, and (peri) menopause. Women's experiences of these harms are also dismissed by pharmaceutical corporations aided by a complicit state, through the mobilisation of idealised norms of femininity which both devalue their (presumed) reproductive abilities and allow the utilisation of individualised and depoliticised processes of 'victim-blaming' in courts in relation to their sexual behaviour (Barton, 1996:1; Finley, 1996:93). Pharmaceutical harms caused to women due to their reproductive abilities are therefore not a new

or novel phenomenon and will undoubtedly continue to occur. As Finley argues: 'For women, a healthy dose of caution about reproductive drugs and bodily devices will have to remain the best medicine' (1996:97).

The neoliberal agenda however gives further opportunities for pharmaceutical profiteering and the exacerbation of gendered pharmaceutical harms towards women. These will continue to occur with decreasing corporate accountability, due to government deregulation measures and infrequent use of the criminal law to punish perpetrators. The responsibilising of individuals for their health under neoliberalism also gives an easy means for pharmaceutical corporations and complicit states to justify any harms caused to them by products that they 'willingly' use or consume (Hillyard and Tombs, 2004; Polzer and Power, 2010). The author is not arguing for more regulation or for more use of the criminal law as both are flawed in holding corporations accountable for harm, as they are made by a complicit state in the interests of the powerful which *includes* corporations (Dukes et al, 2014; Tombs and Whyte, 2015). As critical criminologists have suggested, it is the very historical roots, design and structure of corporations which allow them to evade rather than engage in corporate social responsibility; an impossibility when corporate fiscal health must always be placed above that of its consumers (Bakan, 2005; Tombs and Whyte, 2015). However imperfect, more imaginative solutions need to be used to disrupt the harmful corporation through existing mechanisms, such as existing contract law but with an end 'goal' of the abolition of the corporation (see Tombs and Whyte, 2015; Tombs, 2016:202). In addition to academic advocacy, it is the *collective* activism of women who have been harmed by pharmaceuticals in naming their abuse and its perpetrators as has been argued here, where hope of resistance to the neoliberal state-corporate profit machine remains. Women's experiences or 'subjugated knowledges' are an essential part of re-writing this harmful neoliberal narrative, and in redressing and significantly, preventing these injustices (Foucault, 1980).

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