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The *Poly Implant Prothèse* breast prostheses scandal: Embodied risk and social suffering

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ABSTRACT

This article examines the 2010 scandal surrounding the use and subsequent recall of adulterated Poly Implant Prothèse (PIP) silicone breast prostheses in France. It uses a mixed method approach that includes 12 interviews with French PIP prosthesis recipients, analyses of medical literature, policy documents of French and EU regulatory agencies, and an online forum for PIP recipients. These data are used to explain how the definition of "acceptable risk" in the silicone implants controversy of the 1990s in the US influenced the PIP scandal later on in France. Additionally, PIP recipients had an embodied experience of risk that clashed with the definition of risk used by authorities and some surgeons. The coverage of re-implantation was also defined at different policy levels, leading to variation in patients' suffering. The combination of fraud and lack of recognition from part of the medical system constitutes an example of social suffering for the patients involved. The PIP scandal is a useful case for analyzing the interconnection of embodied experience and professional and public policy definitions of medical risk through the concepts of moral economy and biological citizenship.

1. Introduction

This article analyzes the PIP (*Poly Implant Prothèse*) silicone breast implants scandal, in which a French manufacturer used industrial silicone to produce the medical device for a decade. There is little scientific data on PIP prostheses despite the high public attention they received, and little has been published in terms of medical studies or on the experience of the patients. In this analysis I make reference to a conception of risk as experienced in gendered and classed ways, by individuals capable of politicized understandings (Tulloch and Lupton, 2003). Moreover, I take a pluralistic approach to illness risk. This is because patients have several possible interpretations of risk, especially when biomedicine does not present a definitive answer (Manderson, 2011). In the article I show how the risks associated with an adulterated medical device are interpreted, managed, and experienced at multiple levels: 1) the scientific and regulatory construction of "normal risk" (pertaining to the accepted risk of implant rupture) and the hidden association between this normalized level of risk and that of the corrupted implants; 2) the conflict between surgeons' professional definition of the risk and patients' embodied perceptions of risk; and 3) the public policy interpretations of PIP risk and how these shaped the State's official response to patients, particularly in terms of damages and refund to the women who suffered from implant malfunction. I further recognize that costly or risky practices are also justified through moral constructions of what is valuable and, therefore, of what compensates the cost and/or the risk. Such constructions, which are called moral economies, justify risks in a given context if they, for example, allow one to improve oneself (Edmonds and Sanabria, 2014) or to use one's body to improve one's life (Scheper-Hughes, 2011). Rather than reducing the case to a simple fraud, I point to tensions that characterize the larger context of the event. Public and regulative logics, and market logics, coexist in the production and regulation of medical devices, as well as in the activity of doctors and in public regulation itself. The frame of social suffering is useful to locate the suffering of victims in an economic and legal context. This context goes beyond the fraud and includes the state's response and the surgeons' adherence (or lack of) to the state guidelines. A social suffering approach further shows how the victims' suffering included health and economic damages, as well as the fact that their experience of the risk did not

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receive full recognition or clear answers. I use the term "victim" not to depict the women involved in the scandal as passive; rather, the term was used by several women to emphasize that they were not responsible for what happened.

1.1. The PIP scandal

The PIP scandal came to light in March 2010, when the French Agency for the Safety of Health Products (AFSSAPS, which in 2012 changed its name to ANSM – National Agency for the Safety of Drugs and of Health Products) announced the withdrawal from the market of silicone breast prostheses produced by the French firm *Poly Implant Prothèse* – PIP, because they were produced with a non-homologated silicone gel. Non-homologated silicone gel has not passed the required biocompatibility tests. While there is a variation in the composition of the PIP gel, some problems have been ascertained (see *infra*). These "low cost implants" – as they were described by the French newspaper *L'Humanité* – were ten times cheaper to produce than homologated implants (Jérôme, 2013). An estimated 30,000 women in France alone were fitted with the PIP device (ANSM, 2013: 1). After market withdrawal, an inquiry into fraud and endangerment began in Marseille.

The PIP scandal reached the public in 2011 following the death of a middle-aged PIP recipient in Marseille who was diagnosed with a rare form of cancer, anaplastic large-cell lymphoma (ALCL). PIP owner Jean-Claude Mas was eventually sentenced to four years of imprisonment and fined 75,000 euros for aggravated fraud.

The prostheses are associated with specific physical problems linked to rupture such as irritations, siliconomas (tissue irritations with nodules caused by contact with silicone), and adenopathies (swollen lymph nodes) (ANSM, 2013), psychological suffering, and uncertainty about medium- and long-term effects. Regardless of whether women received the implants for reconstructive or non-reconstructive reasons, the French government decided that all PIP recipients were entitled to free removal of the prostheses. The AFSSAPS advised women fitted with the implants to contact their surgeons or hospitals to inquire about device removal. Likewise cosmetic surgeons were charged with contacting patients who had received PIP implants (AFSSAPS, 2012: 146). France has a universal healthcare system that fully covers post-mastectomy reconstruction, and PIP recipients operated in the public sector were entitled to free reinsertion of new prostheses (although this norm was not fully applied, see *infra*).

1.2. PIP in context: the complex meaning of risk and suffering

Having an adulterated device in one's body entails a specific experience of risk for PIP recipients. This can be analyzed through the concept of embodied risk. Embodied risk refers to risks inscribed in the body of an individual, defined through the diagnosis of premalignant (Kavanagh and Broom, 1998), genetic (Löwy, 2010), or familial predispositions. Beyond environmental and life-style risks, such risks indicate the likelihood of developing a disease (Kavanagh and Broom, 1998). The "embodiedness" of the risk may be considered a variable attribute. For example, Löwy (2012: 215) observes that because of its materiality when compared to purely statistical factors, women perceive breast cellular atypia as *more* embodied than other factors of predisposition such as age or age at first pregnancy. Moreover, Sulik (2009) shows how embodied breast cancer risk leads some patients to develop a "technoscientific illness identity" around the definition and management of the risk. Kavanagh and Broom (1998) underline that the location of the risk inside the patients' bodies makes it harder to cope with, and that traditional answers, like lifestyle changes, are unavailable. One of the main answers is continuous medical monitoring.

The concept of embodied risk can be enlarged to include some types of iatrogenic risk. In the case of prostheses and implants, such risks derive from medical devices that are literally embodied by patients. By definition, iatrogenic risk is estimated in terms of the presumed benefits of the treatment, which serve as a counterbalance to the risks associated with the intervention. Research on medical innovations demonstrates that the proponents of the innovations (such as doctors and medical companies) emphasize the advantages and downplay the risks (Carricaburu, 1999; Löwy, 2012).

Iatrogenic risks are significant factors in cosmetic surgery, where, despite some pathologization of physicality or appearance (Mirivel, 2008) patients do not technically have a health problem but instead an "aesthetic flaw." A vast feminist literature on cosmetic surgery has described it both as a form of domination that imposes gendered appearance norms or as women's agentive responses to the same norms (cf. Miller, 2003). More recent studies on cosmetic surgery have shown how the objectives of the interventions vary with class (Sanchez Taylor, 2012) and ethnicity, and that the interventions can be justified by more general values such as control and improvement of one's life (e.g., Miller, 2003; Essig, 2010; Edmonds, 2013). Reconstructive breast surgery, though linked to oncology, is also motivated by the desire for a "normal" gendered appearance. However, while there is an overlap of techniques and goals between the two surgeries (Greco forthcoming), the experience of cancer sets oncological patients apart. Nevertheless, both groups are exposed to the same undefined risk that is posed by adulterated implants. Moreover, as I will show shortly, in both cases moral economies justify the risk of the operation by defining it as a process of self-realization, coherent with the neoliberal understandings of bodily success and augmentation (see Edmonds and Sanabria, 2014).

In the PIP case, the uncertain nature of both the device risks and the looming controversy about long-term benefits versus detriments merged to create a context particularly prone to conflict. What catalyzed the attention of media was the legal trial – the inherent opposition between a dishonest manufacturer on the one hand and the patients and surgeons, as victims of fraud, on the other. However, informal disagreements and conflicts between patients and doctors are also of importance towards understanding the social dimension of patients' experience of the medical system (Annandale and Hunt, 1998). Moreover, the aftermath of a health scandal forces the patients involved to redefine their relationship with the medical system (Fillion, 2008). As my ethnographic analysis will show, patients also reformulate their relationships with surgeons *during* a medical scandal, in ways that may be invisible in media representations of the events. As the risk derives from a device that has been inserted in their bodies, the PIP recipients are brought to monitor their physical reactions and to look to their doctors for answers. If patients' embodied perceptions of risk do not match the medical framing of risk, they may conclude that medical professionals do not fully understand, and therefore cannot mitigate, their suffering. In such disagreements, the patients not only suffer the "physical" consequences of unrecognized health risks or problems but also a lack of social recognition.

1.3. The dimensions of suffering

Far from being solely an individual experience, the concept of social suffering refers to the intersection of medical conditions and bodily and psychological suffering with the social, political, and economic issues that influence such conditions (Kleinman et al., 1997). Social suffering can also originate from everyday phenomena such as the unequal distribution of duties in the family (Smith-Oka, 2014) or the contradictory pressures in the family (Panter-