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Pregnancy is more dangerous than the pill: A critical analysis of professional responses to the Yaz/Yasmin controversy

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ABSTRACT

The fourth and most recent generation of hormones used in oral contraceptives has stirred a significant amount of debate regarding the safety of these compounds. Drospirenone, a new type of synthetic hormone used in popular oral contraceptives Yaz and Yasmin, has been found by epidemiologists to increase the risk of blood clots when compared to the previous generations of pills. North American regulatory bodies have investigated the health risks of drospirenone and concluded that the increased risks do not require pulling the new contraceptive technology off the market. Instead, the FDA and Health Canada along with several medical associations have actively managed the Yaz/Yasmin controversy through official statements and press releases between 2010 and 2014. This study provides an analysis of these documents and how risk information about drospirenone-containing pills has been presented to the public. The analysis addresses a gap in our knowledge about cultural factors that impact contraceptive risk assessment. Prevalent risk models used by professionals are highlighted and examined through the use of critical discourse analysis methods. More specifically, this paper highlights the main strategies used to put drospirenone risks into perspective and classify it as safe. I argue that while risks related to pregnancy and the postpartum period are overly-emphasized, other risks are downplayed through a selection process underscored by normative beliefs about women's bodies and sexuality. Future research needs to address consumer perspectives and bridge the gap between lay and scientific risk/benefit assessment of oral contraceptives.

1. Introduction

Drospirenone (most often used in combination with ethinyl estradiol) is a hormonal compound that has been used in the latest generation of oral hormonal contraceptives (released in both Canada and the U.S. in the 2000s). Its use is mainly motivated by its properties in combating moderate acne – a beneficial side-effect that has been heavily marketed to potential consumers in ad campaigns. The most popular pills that contain drospirenone are brand names Yaz and Yasmin. The scientific/medical controversy ensued following informal reports in the media of the deaths of young healthy women due to severe blood clots caused by these contraceptives as well as epidemiological studies suggesting increased risk. The pill was widely painted in both the U.S. and Canadian media as 'deadly' with news outlets focusing on the number of deaths associated with the use of Yaz and Yasmin – tens in Canada and hundreds in the U.S. Thousands more have claimed damages in class lawsuits against Bayer across North America. The drugs have been linked to at least 23 deaths in Canada and over 100 in the U.S. as well as thousands of injuries worldwide. Governmental agencies such as Health Canada and the FDA commissioned studies which could assess whether the risk of blood clots or venous thromboembolism (VTE) increases with the new generation of pills containing drospirenone. More epidemiological studies seemed to indicate that drospirenone increases this risk when compared to the risk posed by the previous generation of hormonal contraceptives (Lidegaard et al., 2011). The controversial headlines and news reports continued as more and more inconclusive and conflicting studies were reporting their findings. However, in the late 2000s evidence seemed to suggest that drospirenone does indeed pose a higher risk of VTE than the previous hormonal compounds used in contraceptives. The exact increase varies between different studies: it has been found to be between 1.5 and 7 times increase in risk of VTE when drospirenone is compared to previously-used compounds (Wu et al., 2013). Following such reports, as well as the intensification of public disapproval, regulatory

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agencies and medical associations responded to concerns about risk through public statements and discussions. This study investigates these responses and offers a critical analysis of risk/benefit assessments that professionals have used to evaluate popular, but controversial contraceptives Yaz and Yasmin.

1.1. Hormonal contraceptives and risk: a long debated issue

The history of hormonal contraceptives has been riddled with discussions of safety and risk threshold acceptability. Several historians (Briggs, 2002; Marks, 2001; May 2010; Tone, 2001, 2012; Watkins, 1998, 2007, 2012) have outlined the social context in which such discussions took place beginning with the story of Gregory Pincus, the famous 'father' of the pill, and the team of scientists and doctors that started developing the contraceptive compound. While initial trials proved the pill's efficacy, they did not prove its long-term safety. Doctor Edris Rice-Wray, a faculty member of the Puerto Rico Medical School and medical director of the Puerto Rico Family Planning Association informed Pincus that 17% of the women in the study complained of nausea, dizziness, headaches, stomach pain and vomiting and that a 10-mg dose of Enovid (Searle's brand name for the first pill formulation) would be unacceptable (Watkins, 1998). Pincus and his associate John Rock quickly dismissed these concerns as psychosomatic. Confident in the efficacy of the pill, Rock and Pincus pushed for its approval for market sale.

A couple of years after the FDA approved the pill, discussion emerged within the closed circle of the agency and pharmaceutical companies that the pill posed more serious side effects than previously thought. There were several reports of blood clots, strokes as well as possible links to cancer. As early as 1962, Searle received reports of 132 cases of blood clots in pill users (Watkins, 1998). Eleven of the cases resulted in death. Searle maintained that there was no conclusive proof that the pill caused those deaths.

The publication of *A Doctor's Case Against the Pill*, a controversial book by feminist journalist Barbara Seaman, brought awareness about the pill's potentially dangerous side effects to the attention of the medical establishment, the government as well as the general public. Although the book was not well received in some circles, it eventually influenced U.S. Senator Gaylord Nelson to convene Senate hearings on the safety of the pill. Weighing the pill's risks and benefits was not an easy task. Even those who agreed that the pill posed serious health risks to women were not sure how to weigh them against the benefits. The pill emerged in a social context where the population scare was a very real cultural phenomenon (Seaman, 1969). Moreover, abortions were illegal at the time, leading doctors and patients to view a potential pregnancy as the outcome that must be avoided at all costs. Historically, both in the U.S. and Canada, abortion has been a contentious issue. Contraception was officially illegal in both Canada and the U.S. until the late 1960s, while abortion was only decriminalized in 1988 in Canada and became legal in the U.S. in 1973 (McLaren and McLaren, 1997). As such, abortion was never discussed as an alternative to pregnancy following a contraceptive failure. This remained the case even after abortion became safe and legal.

In 1967, a study published in the British Medical Journal finally established a link between oral contraceptives and the risk of blood clots (thromboembolism). This amplified the controversy at the time. More FDA studies and the pill hearings of the late 1960s ensued. The link between the pill and serious health risks such as cancer and thromboembolism became evident. However, Planned Parenthood and pharmaceutical companies continued to stress the relative safety of the pill. Feminist activists focused their efforts on getting the medical industry to share all the risk facts with pill users.

In later formulations the synthetic estrogen dosage was reduced. This is one of the reasons why the pill is widely perceived as getting progressively safer. However, what has received less attention are the changing hormonal compounds of the combination pill (estrogen and progestin). In its synthetic form, progestin can take many forms. In addition, over the past 20 years, the pill has become a lifestyle drug with added "quality of life benefits." Following the 70s and the pill hearings, the pharmaceutical companies focused less on new methods and formulations and instead have tweaked older versions of the pill and marketed them on the basis of their ancillary benefits. The functioning mechanism and relative health risks remained the same. For example, one popular brand, Ortho-Trycylen-Lo, was advertised as an acne treatment. The fourth and most recent generation of pills involves the drospirenone controversy discussed here.

1.2. Risk as a social construct

Sociological approaches to risk are a response to the need to analyze technological innovations (Beck, 1992; Lupton, 2013; Zinn, 2008). In analyzing issues of risk as they relate to oral contraceptive pills, I will draw on the sociocultural approach originally developed by Mary Douglas (Douglas, 1986, Douglas and Wildavsky, 1983). Douglas (1992) emphasizes the cultural and political dimensions of the concept of risk in public policy. She argues that an analysis of risk has to include cultural biases and that risk can be generally understood as a social construct (Douglas, 1992). Different groups of individuals look at different risk types and characteristics as a consequence of their specific social position, their part in organizations, and the organizations' role in the wider political culture (Gabe, 1995; Lupton, 2013). Medical professionals, as a result of their positionality, might be removed from the layperson's perspective on health-related risks. While lay knowledge of risk has been emphasized in some instances (Gabe, 1995; Lupton, 2013; Zinn, 2008), this study focuses on expert knowledge and its cultural embedding into gendered norms. From a conventional medical view, risk analysis can be said to involve "the scientific elucidation of damage mechanisms from different natural or technical processes, and the quantification of probabilities and consequences" (Williams et al., 1995, p.120). However, alternative notions of risk can and do exist (Franklin, 1998; Williams et al., 1995). These notions stem from the fact that scientific evaluations rarely take into consideration the social context in which risks occur. They also do not take into account how social norms might influence a process that is deemed scientific and objective.

While Douglas's cultural theory does not specifically question technical procedures for the measurement of risk, it does criticize the depoliticization of risk issues. Douglas (1986) has been critical of the way in which institutions use risk discourses to control human behavior uncertainty and to reinforce norms. The sociocultural perspective focuses on the ways in which risks are selected and presented to the public. As such, it critiques the scientific assumption that individuals are rational agents making decisions based on rational calculations. Decisions regarding what data should be presented to the public have been instrumental in risk perceptions of hormonal contraceptives, for example.

In the sociocultural tradition, scholars have documented the ways in which risk discourses construct reality and influence individual perceptions (Fortun, 2004: Fosket, 2004; Langston, 2008; Schmid, 2004; Timmermans and Leiter, 2000). Some risks have been continually downplayed by the media and governments. One example is the lack of strict regulations around the use of endocrine disruptors (Langston, 2008). However, risks can also be emphasized in order to mobilize populations. Such is the case of post-Chernobyl discourses that have been deployed strategically to gain authority,