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Promoting Public Trust: ESCROs Won't Fix the Problem of Stem Cell Tourism

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We agree with Greely (2013) that embryonic stem cell research oversight (ESCRO) committees have probably helped to promote ethics in stem cell research (SCR). In this commentary, we draw attention to a few issues that we suspect neither ESCROs nor any current form of governance of SCR is likely to fix. These issues cast a certain degree of social skepticism toward SCR that may prevent some publics from trusting SCR and in other cases, may actually lead to a loss of public trust. These include (1) a lack of a suitable ethical resolution over the moral status of human embryos and the harms to women as ova providers and whether eggs and embryos should be used for SCR, (2) the public's unmet expectations of the therapeutic promises from SCR, and (3) the delivery of bogus therapies to patients in what is commonly referred to as the stem cell tourism industry.

Public trust and public support for science are complex and multifaceted: There is no single "public" and different publics have differing levels of trust (Resnik 2011). In a similar vein, how individuals support science is also intricate, as some may support it through financial donations, performing research or teaching science, participating in clinical trials, voting for a president or other elected officials who are pro-research, or donating their body as cadavers to support medical training (Master and Resnik 2011a). In addition, there is no established causal relationship between public trust and the public support for science (Master and Resnik 2011a; Resnik 2011). Although it can help promote public trust, good governance does not guarantee it. Also, those who are troubled by SCR because they believe in the moral worth of human embryos will never trust the regulatory system, irrespective of how much oversight we place on the field. In addition, public trust in SCR may diminish as awareness of unmet promises and the harms caused by the stem cell tourism industry increase.

REHASHING MORAL STATUS

In the United States, there is an intractable debate in SCR concerning the moral status of human embryos, and many believe that embryos should never be used in research. Even those who do not place special moral value on embryos are concerned about potential harms to women who donate eggs to create embryos for research. Scientific research on alternatives to human embryonic stem (hES) cells and academic scholarship on the moral status of the embryo have failed to fully resolve the ethical issues at hand. There are currently no real replacements for eggs and embryos for SCR, including induced pluripotent stem (iPS) cells.

Although still quite promising, several lines of research are fuzzy on the potentiality and immunogenicity of iPS cells and thus their clinical potential remains questionable. In addition, current bench research using iPS cells relies on the continued use of hES cells, indicating that iPS cells are not replacing the need for hES cells (Scott et al. 2011). Arguably, human eggs and embryos, at least for the time being, are required for SCR and clinical applications. To appease those who have ethical qualms about hES cell research, some sort of policy mechanism would be needed to ensure social trust with the understanding that one day, non-egg and nonembryonic sources will be used for SCR (Master and Crozier 2012). One could argue that a temporary ethical and political compromise on the moral status and harms to women debates is needed where we continue to use eggs and embryos until a point where they are no longer required for research (e.g., if iPS cell technology begins to demonstrate clinically efficacy) (Master and Crozier 2012). Yet we contend that such a compromise is not for everyone. It is also doubtful that further ethical reflection will settle the debate, and possibly the only way to resolve the issue is to absolve the need for eggs and embryos in SCR. Perhaps one day this will be achieved.

CLINICAL PROMISES, UNMET EXPECTATIONS, AND PUBLIC TRUST

There has been considerable hype that the potential investment in SCR will generate novel treatments and be a major economic engine (Caulfield 2010). Although there are no significant data showing that hype in science leads to a loss of public trust and support for science, this doesn't mean it can't happen (Master and Resnik 2011a). As the public becomes more aware that its investment in SCR is not bearing fruit, continued public and political support for SCR may dwindle and research funds could be diverted into other promising areas. Robust oversight mechanisms governing the conduct of stem research are not likely to have much of a positive impact on public trust if therapies or other products are not forthcoming. So how can we ensure continued support for SCR? For starters, those who overtly exaggerate timelines and the clinical promises of SCR need to be conscious of how hyping research can undermine public trust, and they should make forecasts that are reasonable and measured (Master and Resnik 2011a). We believe people generally understand the value of stem cell and other areas of biomedical research in that it serves to generate knowledge even if it doesn't immediately lead to a successful clinical product.

THE MOST SIGNIFICANT THREAT: STEM CELL TOURISM

Although public trust in SCR is likely affected by not having some form of ethical resolution, the most significant threat to public trust is the continued growth of the stem cell tourism industry (Caulfield et al. 2012). Stem cell tourism is an Internet-based, direct-to-consumer marketed industry where patients travel to destinations outside their home base (usually to another country) in order to receive untested and unproven clinical stem cell interventions. Perhaps spawned by the hype surrounding SCR, many rogue clinics are charging hefty sums for providing interventions ranging from placebos to transplanting stem cells or stem cell products that could lead to tumors, lesions, tremors, and even death (Master and Ogbogu 2012; Zarzechny et al. 2012). To prevent this problem, many scholars have called for enhanced international oversight and enforcement (Sipp 2010), but we have argued that international guidelines or regulations have little teeth, as enforcement is likely to be weak and that most regulations function within a nation, not internationally (Master and Resnik 2011b). Moreover, unscrupulous individuals may simply break the rules and accept penalties, especially when they are not severe or could simply move clinic locations to a more permissive regulatory environment (Master and Resnik 2011b).

The International Society for Stem Cell Research (ISSCR) has taken a leadership role in dealing with this problem by developing clinical translation guidelines for SCR. It also

created a website where patients and others can ask ISSCR to look into stem cell clinics, but some clinics threatened legal action, which resulted in shutting down the website. Despite these noteworthy attempts, fraudulent stem cell clinics continue to flourish. Although increased international governance may help, it is unlikely by itself to make a significant dent in the industry. Curbing stem cell tourism will most likely require a concerted effort of education to raise awareness of the problem, combined with governance, active enforcement, and the responsible sharing of stem cell lines and products between scientists. If stem cell tourism continues to flourish and more adverse events occur, these events are likely to lead to public distrust that could damage legitimate SCR. The marketing of unproven stem cell interventions and media reports of sports figures and other celebrities who have undergone stem cell interventions help generate an expectation of efficacy that is unlikely to be met and over the long term, could lead to public disappointment.

Clinical and SCR abuses are unlikely going to be stopped by ESCROs or potentially any form of domestic or international governance system. The establishment of self-governance mechanisms placed by scientists and other professional organizations will not persuade those opposed to SCR to trust the system. Even proponents of SCR are disturbed by the phenomenon of stem cell tourism, and international governance by itself is unlikely to stop these abuses. To maintain or promote public trust in SCR will require, at minimum, three strategies: (1) developing non-ova and nonembryonic sources of stem cells for stem-cell-based therapies, (2) ensuring that SCR lives up to its promise and develops clinically safe and efficacious therapies, and (3) taking steps to quell stem cell tourism.

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