Whose cells are they? Public perceptions about owning autologous cells

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Identity and ownership issues in the regulation of autologous cells
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The growing international industry of unproven stem cell therapies around the globe has increasingly focused on using autologous cells and promoted therapies as services that enable patients to access the medical potential of their own cells. Mr Sipp's examination of a set of public comments submitted to the US Federal Drug Administration reveals strong public opinions about the ownership of autologous cells lying with the individual they come from. However, this appears to contradict current legal interpretations of ownership rights for unprocessed cellular materials, which may have to be revisited and revised to address these issues.

What questions & challenges are raised?

Efforts to manage and regulate unproven stem cell therapies appear to have done little to curtail the ever-growing number of clinics selling these treatments around the world. Many unproven treatments often lack scientific reasoning, are costly and offer no proof they are either effective or safe. Yet, numerous patients, carers and patient groups support reducing regulations to make these therapies more accessible, particularly therapies that use cells collected from the patient being treated (autologous cell therapies). In 2016 the US Food and Drug Administration (FDA) provided an opportunity for the public to submit comments about draft guidance regulations being considered on the use of autologous human cells and tissues for medical treatments. Mr Douglas Sipp from the RIKEN Centre for Developmental Biology and Keio University School of Medicine examines these public comments in his recent perspective article and discusses the strong opposition most comments expressed to any form of FDA regulation over autologous cells. Several themes were observed in these comments, which Mr Sipp proposes are capitalised on, and possibly coordinated, by the industry of unproven stem cell therapies.

What insight & direction does this give for research policies?

Mr Sipp's analysis of public comments shows a clear prevalence in opinions emphasising ownership, access, and personal rights over autologous cells and therapies. These public opinions appear to be reinforced by businesses persuading patients that clinics provide services that allow individuals to take action, make their own healthcare decisions and access the medical potential of their "own cells". However, these public and business perspectives conflict with the current legal standing on the value and ownership of autologous biological material. This conflict could present issues for the FDA to establish and enforce regulations on unproven autologous cell therapies. Mr Sipp suggests that laws should be revisited to clarify this ambiguous question of who, if anyone, owns autologous cells. However, it is likely that addressing unproven autologous cell therapies will require alternatives to existing regulatory and enforcement approaches, as patients see regulation as restricting consumers. This is further complicated by evidence that shows patient education measures to curtail demand appear relatively ineffective. Exactly what approaches are needed to manage this growing industry remains a current challenge.

What background and point are discussed?

In 2016 the FDA provided the opportunity for the public to comment on proposed guidance documents that addressed four topic regarding the regulation and use of autologous tissues and cells. The online FDA forum received a total of 6,962 comments. Surprisingly, Mr Sipp's analysis of 400 randomly selected comments found that only three submissions actually addressed any of the four discussion topics. The vast majority of comments (383/400 or ~96%) expressed opposition to any form of government regulation at all. Mr Sipp notes that special interest groups likely made efforts to influence this public comment process, as there were many comments (64/400 or 16%) containing the same statement, "My cells are MY cells. They are not a drug, they are part of my body". Analysis of the remaining comments reveals several general themes. Suspicion was expressed by many individuals, specifically the FDA's treatment and reference to autologous cells as drugs, with over half (227/400 or ~57%) of comments using the word 'drug' in their comment. A subset of these presumed that the FDA categorizes autologous cells as drugs because it has been corrupted by pharmaceutical interests and establishes regulations to benefit the pharmaceutical industry. Another voiced theme in comments was that FDA regulations violate human rights over how one can use his or her body and body parts. The most prevalent theme Mr Sipp found in comments was that FDA regulations infringe on individuals' ownership of their body and body parts. Words about "ownership" or "my own" cells or body appeared in 75% (300/400) of all the comments examined. Mr Sipp remarks that US law regards cells, tissues and other parts of the body as no one's property unless they are modified and given value by the skill of another individual, an interpretation that generally conflicts with the views being expressed. Many comments about ownership also view FDA regulations as targeting and constraining consumers, when in fact, the FDA only has jurisdiction to regulate how businesses produce, market, and distribute products. Mr Sipp discusses in detail how clinics selling unproven therapies have successfully profited from (and promoted) these public views and the distrust of government oversight. Furthermore, clinics have shifted towards using autologous cell treatments over the years rather than cells from other sources or donors. This industry-wide convergence on autologous cell therapies is partly due to liberal interpretations of government regulations, but is also because autologous treatments better align with public sentiments about cell ownership and freedom for personal choice.