# To the editor:

## Making business out of patients?

Access to healthy or diseased human cells is in high demand by the biomedical community. Despite valuable information gained using animal models, the knowledge they yield about the mechanisms underlying human disease is limited because of the myriad differences between lower animals and humans in normal and disease physiology. Analyses of human tissues and physiology are necessary to unravel mechanisms leading to disease and to design safe and effective new therapies.

Access to primary human cells is tightly regulated and restricted in academic institutions. A large and appropriate amount of oversight and paperwork is required to ensure that research involving humans complies with standards designed to protect patient safety and interests that are set by institutional and national committees. Investigators desiring access to tissues from healthy volunteers or patients must obtain approval of specific procedures and sample usage from these committees, providing them with an informed consent document and a summary of the aims of the research, which must be read, understood and signed by the participants. These are necessary steps, although they may delay projects and require significant investigator and institutional effort.

Regulations regarding the acquisition and use of human tissues may vary across nations and cultures. For instance, human embryonic stem cell research is banned in some countries but allowed in others. Despite these differences, most countries agree on the fundamental need to regulate the procurement, use, and distribution of human primary tissues, in order to make research transparent and to honor the wishes and contributions of patients who provide their tissues as research samples.

However, the existence of commercial establishments that sell human cells from healthy donors (for example, hematopoietic stem cells or other mature cell subsets from blood, cord blood, or bone marrow), discarded tissues from spontaneous abortions (fetal brain, liver, and embryonic stem cells), and, most surprisingly, from newly diagnosed and relapsed patients suffering from devastating diseases (leukemias, lymphomas, myeloma) is a matter of concern. This is not an isolated issue. The provision of cells for research and future clinical applications seems to represent an emerging industry, as evidenced by companies including StemCell Technologies (Vancouver, BC), StemLifeLine (San Carlos, CA), Geron Corporation (Menlo Park, CA), ViviCells International (Evanston, IL), NeoCells (Evanston, IL), LifeBankUSA (Cedar Knolls, NJ), and Cryo-Cell International (Oldsmar, FL), among many others.

This scenario suggests many questions that may set up a platform for a debate. How do these companies ethically obtain and store enough human cells from patients to be sold worldwide? Many noncommercial entities, such as academic medical centers and tissue banks, also recruit healthy volunteers to donate renewable cells or tissues such as blood or bone marrow, collected with limited risk or inconvenience, often in return for limited remuneration to the donor for time and effort. Moving this process to a for-profit situation raises concerns, but it is not without precedent (eg, payment for blood components by blood banks, or payment for human serum for production of therapeutic materials). However, the sale of disease samples from patients, including, for instance, primary leukemia or lymphoma cells, is more disturbing. How are these patient-donors recruited? Are they paid? If so, is there any chance they are delaying appropriate therapy in order to donate more cells for pay? Presumably, the companies who recruit these donations have suitable signed informed consents from all donors, but there is no way that donors can consent to the actual research ultimately conducted using their cells, because the companies to whom they donate have no prospective knowledge about the types of research their customers will conduct with the cells. Are patients and healthy volunteers recruited by the companies aware that their cells are being used for profit? Are national organizations overseeing health, patient safety, and research ethics aware of this? What are the positions of national authorities and company investors regarding the relationships between the companies and the people whose cells and tissues they obtain?

Science serves society. Scientific research is funded mainly by taxpayers through government-funded projects and entities. I believe the current scenario represents a lack of respect for patients and is biased against academic and nonprofit researchers who desire access to clinical human samples but cannot afford to purchase them from corporations. If these businesses are legal and are going to continue, a suggestion would be to have them regulated by national health authorities who should implement suitable guidelines governing procurement, storage, and distribution of human primary cells and have oversight over informed consent documents. Although costly, national health authorities might also set up a nonprofit public "human primary cell core facility" containing quality-controlled cells from multiple sources and diseases (similar to public DNA banks or stem cell banks). Alternatively, to reduce costs, government funders of health research might launch strategic grants to help fund for-profit companies willing to harvest, isolate, store, and distribute high-quality healthy or diseased human cells from persons who willingly give their written informed consent to donate their cells for research, making them available to academic laboratories at low cost. Government funders and regulators should participate on the external scientific advisory boards of such companies to ensure that governance guidelines, ethical principles, and scientific transparency are followed. Maintaining access to human primary healthy or diseased cells should be a project for public good rather than private profit.

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