On April 11 to 13, the Vatican hosted “Regenerative Medicine: A Fundamental Shift In Science and Culture,” the second International Vatican Adult Stem Cell Conference. The stated goals of the conference were “To discuss and understand the importance of scientific advancements in the paradigm shift toward regenerative medicine, with a particular focus on adult stem cell therapies and the interconnections between research, faith, ethics and culture...[and to] foster an open dialogue amongst researchers, physicians, philanthropists, faith leaders and policy-makers in order to help identify clear, unmet medical needs throughout the world that can be addressed through the development of cellular therapies that will reduce human suffering.” The schedule (http://adultstemcellconference.org/the-conference/schedule/) consisted of an array of topics, including presentation of clinical trial results, patients discussing what its like to live with a chronic illness, seminars on the challenges in manufacturing cells for human use, and discussions of the political, ethical, cultural, and societal aspects of stem cell research. The range of clinical topics spanned diabetes mellitus, multiple sclerosis, autoimmune disease, heart disease, traumatic brain injury, aging, wound healing, and cancer. In some cases, patients who had participated in clinical trials were present and discussed their experience.

This was not, strictly speaking, a scientific meeting, although there was a robust presence of scientists, including a Nobel laureate; the mean h-index of the scientists who spoke at the meeting was 54. The meeting, however, was designed to be much broader in scope and included clinicians and scientists working on cell-based therapies, regulators and policy-makers, clergy and patients and their families. Unlike a typical conference, this meeting attempted to broach some of the societal, cultural, regulatory, and ethical issues raised by scientific session, this meeting was designed to remain adherent to the regulations of the European Union. In a slightly more liberal fashion, but is nonetheless required in a medical context. Italy may, therefore, apply hospital exemption rules to advanced medicinal products, which include cell therapies. Italy may, therefore, apply hospital exemption rules in a slightly more liberal fashion, but is nonetheless required to remain adherent to the regulations of the European Union.

Next, in a statement that is highly insulting to the patients who attended the meeting, the editorial implied that the meeting was orchestrated to influence the Italian Parliament to deregulate stem cell medicine. This concept seems to have been conjured up by the author(s) of the editorial, as there was nothing at the meeting having anything to do with Italy’s Parliament. As noted in the Nature editorial, this was the second Vatican meeting, the first being held nearly 2 years ago. The planning for this meeting began over a year ago, and it was, therefore, fairly clear that there was no connection between the Vatican meeting and anything in the Italian legislature. This manufactured connection between Italian legislature and the Vatican meeting not only discloses the single-minded intention of the author(s) to create the appearance of a conspiracy, but also openly reveals a willingness of the anonymous editorialist(s) to ignore facts. Italy is a member of the European Union. As such, any kind of clinically applied cell therapy is regulated by the European Medicines Agency, which has very clear cut rules for so-called advanced therapeutic medicinal products, which include cell therapy. Italy may, therefore, apply hospital exemption rules in a slightly more liberal fashion, but is nonetheless required to remain adherent to the regulations of the European Union.

In yet another derogatory comment, the author(s) of the editorial state their judgment that the Vatican is scientifically naïve (although it is doubtful that this verdict is based on an analysis of evidence, as would be expected of a scientific journal). Meanwhile, the editorial states that “patients should be exposed to experimental treatments only when answer periods after each talk, the meeting program included many breaks and social gatherings designed to provide an opportunity for participants and attendees to interact, engage in discussions, and ask questions. As participants, we can verify that we had many interactions with people with diverse viewpoints whom we would never have met at the meetings we typically attend.

It was sad and disappointing, given the reality of the meeting, that Nature decided to publish an anonymous editorial that was highly misleading, not supported by facts, and essentially an ad hominem attack laced with the type of invective one expects to find in the tabloids, not an esteemed scientific journal.

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The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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Perspective

Angels and Demons: Part II

Douglas W. Losordo, Andreas M. Zeiher

In his 2000 best-selling novel, Dan Brown tells the fictional story of an apparent plot by the Illuminati, the self-proclaimed "enlightened ones," against the Vatican. Apparently life truly does sometimes imitate art.

In his 2000 best-selling novel, Dan Brown tells the fictional story of an apparent plot by the Illuminati, the self-proclaimed "enlightened ones," against the Vatican. Apparently life truly does sometimes imitate art.
safety and efficacy is assured.” We are just wondering how one
would know about safety and efficacy before the experimental
treatment has been, well, tested?

It is easy to stand on the sidelines, criticizing those who
are attempting to help patients by developing novel therapies
as scientists desperate to hawk a message that their therapies
must be speeded to clinical use. This type of cynicism has
been noted repeatedly in the history of medicine. It has been
said that one can always identify the pioneers because they are
the ones with the arrows in their back.

The Nature editorial speaks of raising false hope of quick
fixes; however, the participants at the meeting simply pre-
sented data from clinical studies overseen by Food and Drug
Administration or European Medicines Agency, just as is done
at many other medical meetings. The real question is, why
is there a problem with sharing data? It is hard to escape the
conclusion that the highly emotional editorial is simply a reac-
tion to the fact that certain biases are being relentlessly over-
whelmed by data.

Those biases can also lead to flip-flops of logic. In the cur-
rent editorial, China is portrayed as a malignant force because
of its apparently lax policy toward the use of adult stem cells.
However, in a 2010 editorial, the United States was admon-
ished to act more like China when it comes to allowing the
use of embryonic stem cells.2 Meanwhile, the presentation
at the Vatican meeting of data from multiple clinical trials
involving hundreds if not thousands of patients, conducted
by reputable investigators with the approval of appropriate
regulatory bodies (Food and Drug Administration and
European Medicines Agency), is dismissed as smoke and mir-
rors. Is this a position that promotes science? Where is the
balance, never mind compassion for patients?

We are in a new era of medicine, with many challenges
ahead, as well as much hope by and for patients. There is much
debate on how to pursue these new therapies. Many have ques-
tioned whether any regulatory body should be able to control
how patients use their own cells to treat themselves, as long
as manufacturing processes of the cellular product and deliv-
ery comply with regulatory rules. In this regard, one wonders
if, under the current conditions, autologous bone marrow
transplantation could have been developed.

Legitimate questions should be addressed on the basis of
data, objective evidence, and rational discussion, and must in-
volve all the stakeholders, including patients.

The trail leading to the use of cell-based therapies to treat
diseases is being blazed by a courageous few who would
rather try than sit on the sidelines and use distortion and in-
uendo to criticize. We applaud the Vatican for attempting to
shed some light on this subject by inviting a broad array of
individuals to discuss the challenges openly and attempt to
find solutions.

Disclosures

None.

References

2. Human embryonic stem cell research in the us: time for change? Nat Cell
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