



APR 26 2010

Ken Cornetta, M.D.
President
American Society of Gene and Cell Therapy
555 East Wells Street, Suite 1100
Milwaukee, Wisconsin 53202-3823

Dear Dr. ^{Ken} ~~Cornetta~~:

Thank you for your letter of March 10, 2010, outlining your recent discussion with the directors of the Institute and Centers of the National Institutes of Health (NIH) and staff in the NIH's Office of Biotechnology Activities (OBA). We appreciate the time and effort you took to engage with our agency, and I thank you for sharing your perspectives about the recurring themes that arose during your discussions across the campus.

The issues you are exploring as a Society—innovations in funding models for translational research, regulatory science and review, and coordination and communication across NIH research programs—are critically important, and your suggestions about the steps the NIH should take to further advance translational research are very concrete and helpful. As we consider the optimal resources and infrastructure for advancing such promising fields as gene and cell therapy, we will certainly take your specific recommendations about milestone-driven approaches, research and support services, and additional collaborative activities into account. The NIH is also actively engaged in exploring ways in which investigators could partner with the NIH Clinical Center to carry out collaborative research. For example, a working group of the NIH Scientific Management Review Board, a congressionally-mandated body that provides advice on the organization of the NIH, is currently analyzing the regulatory and policy mechanisms needed to enable such partnerships.

Your points about our new Regulatory Science Initiative are also timely. This Initiative is intended to address the very concerns you raise by providing an evidence-based approach to fostering the development and approval of clinically useful products. Projects funded under this Initiative are aimed at improving the "review readiness" of clinical studies and informing regulatory decision-making. We hope that improvements in these critical domains will facilitate the translation of research discoveries into new health products.

Finally, we are pleased to be a part of the ASGCT annual meeting next month through the participation of the OBA staff. Your meeting will provide another venue for the NIH to engage on these issues and to continue a dialogue on common concerns.

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Thank you again for your letter. The NIH looks forward to working closely with the ASGCT as we both endeavor to advance science and contribute to the betterment of human health. I will also send a response to Dr. Barrie Carter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins". The signature is fluid and cursive, with a large initial "F" and "S".

Francis S. Collins, M.D., Ph.D.
Director