National Cancer Advisory Board (NCAB)
***ad hoc* Subcommittee on Experimental Therapeutics**

8 February 2024
11:05 a.m.–12:05 p.m. EST

Virtual Meeting

SUMMARY

Subcommittee Members
Dr. Richard J. Boxer, Chair
Dr. Rose Aurigemma, Executive Secretary
Dr. Nilofer S. Azad
Dr. Anna D. Barker
Dr. Andrea Hayes Dixon
Dr. Howard J. Fingert
Ms. Julie Papanek Grant
Dr. Amy B. Heimberger
Dr. Nikan Khatibi (absent)
Dr. Susan Thomas Vadaparampil (absent)
Dr. Ashani T. Weeraratna

Other Participants
Dr. John D. Carpten, Chair, NCAB
Dr. James Doroshow, National Cancer Institute (NCI)
Ms. Ysabel Duron, NCAB
Dr. Michelle Heacock, NCAB
Dr. Paulette S. Gray, NCI
Dr. Douglas R. Lowy, NCI
Ms. Anne Lubenow, NCI
Dr. Ana Navas-Acien, NCAB
Ms. Thu Nguyen, NCI
Dr. W. Kimryn Rathmell, Director, NCI
Mr. Ricardo Rawle, NCI
Dr. Dinah Singer, NCI
Dr. Fred K. Tabung, NCAB
Dr. Karen M. Winkfield, NCAB
Ms. Joy Wiszneauckas, NCI
Ms. Sally Paustian, The Scientific Consulting Group, Inc., Rapporteur

Review of Draft Mission Statement Updated Language
Dr. Rose Aurigemma, Associate Director, Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), NCI

Dr. Rose Aurigemma provided a brief overview of DTP and its mission to support and assist the extramural community in promoting translation of new therapeutic concepts toward clinical use. In the preclinical research space, DTP provides grants, a suite of services and resources, and the Stepping Stones Initiative, which helps fill knowledge and data gaps in the translational pathway for new therapeutics. DTP participates in the NCI Experimental Therapeutics Program (NExT) program, a mechanism for business, academia, or intramural applicants to request application support. The NExT program encompasses three areas. The first area is discovery, which is managed by the Chemistry Biology Consortium. The second area is preclinical development, through which DTP promotes small molecules and biologics. The third area is clinical development, which is overseen by the NCI DCTD Cancer Therapy Evaluation Program (CTEP). Dr. Aurigemma noted that this information was presented in depth during the November Subcommittee meeting and encouraged members to contact her with any questions.

This Subcommittee was established in December 2006, as NExT was being formed, and the Subcommittee has since evolved, making the mission statement outdated. Because DTP now offers many support avenues for translating novel processes into clinical use, this Subcommittee reconvened several

years ago to assess how the field has changed and how members can provide input on which areas of the translational critical path were not being adequately addressed. DTP began to support cell therapy more strongly and held a number of workshops to connect with partners about possible collaborations. Dr. Aurigemma pointed out that the updated mission statement generalizes the support but retains the charge to ask the Subcommittee to help the NCI identify areas of innovation or opportunities that can be explored to bolster programs fostering translational research.

Discussion and Adoption of Mission Statement Language

Dr. Amy B. Heimberger, serving as Acting Chair for a portion of the meeting, opened the discussion. Dr. Andrea Hayes Dixon commented that the statement is succinct and needs no revision.

Dr. Howard Fingert remarked on suggestions sent in advance and requested information on which projects succeeded or failed; he indicated that industry collaborations can help provide this information. Dr. Aurigemma agreed that reviewing successes and failures is important to help programs evolve, suggesting that metrics could be gathered before the next Subcommittee meeting. She noted that DTP prides itself on helping investigators understand whether their products are feasible, and the NCI wants to de-risk new therapeutics to make them attractive to industry. DTP often follows up with investigators about the status of projects, but sometimes DTP loses track of the products. She noted that the NCI supports risky projects that offer the opportunity to learn from each outcome, and she added that DTP has a robust consultation service to help applicants understand how best to bring their therapeutics to market. Dr. Heimberger suggested building metrics into the next iteration of the program and assessing the most common "no-go" reasons in the consultation service.

Dr. Barker pointed out that many companies fail because of poor adherence to good laboratory practice (GLP), which is difficult to support in the academic world but is something in which the NCI can provide training. She noted that the NCI has a long and rich history of developing cancer drugs and a responsibility to help continue progress in this area. Dr. Heimberger suggested developing a white paper on the NIH perspective on why programs fail; Dr. Aurigemma commented that she would need to refer such a project to the clinical arm of DTP. She noted that DTP spends significant time on investigator education, and the robustness of assays has a strong effect on success.

Dr. Fingert supported an edit to the mission statement that would favor the use of updated protocols because many investigators work with old textbooks, whereas industry is more likely to keep up with new guidance. He also suggested adding "research programs" to the mission statement in the third paragraph to emphasize the Subcommittee's interest in the research being fostered. Dr. Aurigemma pointed out that advice from the Subcommittee can include opportunities to develop tools for the extramural community. Dr. Fingert suggested adding a reference to drug development tools, a term commonly used by the U.S. Food and Drug Administration (FDA), because academia has had significant problems in this area in the past. He indicated that drug development tools can include biomarkers and that a biomarker consortium is available that could help speed the efficiency of drugs. Dr. Aurigemma pointed out that the Cancer Diagnosis Program supports some of these efforts.

Dr. Gray reminded attendees that a mission statement should be succinct and convey the overall interests of the Subcommittee but not address every detail. Dr. Kimryn Rathmell added that the current draft seems more like a program outline than a mission statement. She pointed out that the mission of the Subcommittee is to bring discovery to clinical therapeutics, and the other included information is more supportive.

Dr. Barker pointed out that the FDA is moving quickly to regulate laboratory-developed biomarker tests, which will have significant effects on the academic community for which the Subcommittee can help its colleagues prepare.

Dr. Richard J. Boxer, Chair, commented that the mission statement should be broad enough to cover many areas but should not exclude others. He asked if the current draft should be revisited.

Dr. Barker emphasized the importance of prioritization to help the NCI improve its drug development efforts. Training is most important, but the difference between "translatable" and "commercializable" development must be defined, and translation must be conducted with a rigor appropriate for commercialization.

Dr. Heimberger pointed out that staffing changes have delayed updates from the director of her Cancer Center about the vision for this Subcommittee's role. Dr. Aurigemma agreed that this area is lacking and suggested that the topics raised fall under the umbrella of the current mission statement, which the Subcommittee can refer to when choosing which areas to focus on in subsequent meetings.

Ms. Julie Papanek Grant pointed out that experimental therapeutics are distinct from medicines and that if the mission statement emphasizes regulatory approval to the exclusion of other parts of the process, it does not encompass the entire scale of the effort. Dr. Rathmell agreed that the charge must be broader than FDA approval.

When asked about the focus on the NExT Program, Dr. Jim Doroshow explained that the Subcommittee was formed at the same time as NExT, which brought together many pipelines in the portfolio. A more general mission statement could be drafted that encompasses a wider swath of therapeutics.

Dr. Boxer suggested that the Subcommittee not present the mission statement at the full NCAB meeting and recommended forming a small group to review and refine it in advance of the next meeting. He commented that discussing the mission statement allows the Subcommittee to consider its future goals. Drs. Boxer and Aurigemma will coordinate this effort.

Adjournment
Dr. Richard Boxer, Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles
Dr. Boxer adjourned the meeting at 12:02 p.m. EST.

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Dr. Richard J. Boxer Chair	Date	Dr. Rose Aurigemma Executive Secretary	Date