

September 15, 2010

The Honorable Cynthia Nava New Mexico State Senator 3002 Broadmoor Las Cruces, NM 88001

The Honorable Mimi Stewart New Mexico State Representative 313 Moon Street NE Albuquerque, NM 87123

Dear Senator Nava and Representative Stewart:

I am writing in response to Senate Joint Memorial 19 and House Memorial 36, which request the Department of Health to make recommendations to the Legislature on how to expand access to cancer clinical trials to all parts of the state.

In the United States, almost 90% of eligible pediatric cancer patients participate in clinical trials (trials), contributing to an overall cure rate for childhood cancer that exceeds 75% (Ries LA, Eisner MP, Kosary CL, et al. SEER cancer statistics review1975-2002. Bethesda; MD: National Cancer Institute, 2005). Only 5% of adult cancer patients participate in trials. With so few adults participating in clinical trials, adult cancer research is not as extensive as pediatric, which may contribute to the lower cure rate for adult cancers.

Researchers have identified a number of barriers to clinical trial enrollment, including lack of public awareness, reluctance by physicians to refer patients to trials, distrust of clinical researchers, inconvenience of participating, and concerns about the costs of participating in clinical studies (NIH website). In New Mexico, "the two main reasons for nonparticipation are lack of protocol availability and lack of interest on the part of the patient or physician. More patient education must be planned to improve clinical trial enrollment" (Journal of Clinical Oncology, 2005 C.F. Verschraegen, et al.).

Many trials are available to New Mexican cancer patients in Albuquerque, Santa Fe and Las Cruces. Because of their size, these cities have the infrastructure and skilled staff necessary to conduct trial activities. They also have the patient population base required by the pharmaceutical or bio-technology companies to complete the trial.



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The gaps in availability outside of the Rio Grande corridor are primarily due to a lack of appropriate patient population size and the infrastructure to support clinical trial activities. Many do not have the specifically trained staff required to comply with clinical trial guidelines.

In order to expand participation outside the Rio Grande corridor, New Mexico could consider using a model similar to the one developed for the Eastern Shore of Maryland and adopted by the US Department of Health and Human Services as part of the National Best Practice Initiative. It includes ongoing public education on what clinical trials are being conducted and their potential benefits. This involves going into communities, attending community events and obtaining support from local leaders to help get the word out; providing continuing education for local community health care professionals including physicians, nurses, and nurse practitioners; and providing the infrastructure, the clinical trial nurse or clinical research assistant, and computers for data tracking. By using this approach in a rural community, Maryland has seen a 40-fold increase in clinical trial participation (BenchMarks interview with Claudia Baquet, MD).

Two organizations in New Mexico are undertaking portions of this approach already:

- The New Mexico Cancer Care Alliance (NMCCA) is a science and education charitable organization whose mission is to provide local access to the most up-to-date cancer research for both physicians and patients. It has a network of health care institutions and approximately 120 cancer treatment physicians in the Rio Grande corridor and is in the process of expanding throughout the state. Many Alliance physicians treat patients from throughout the state.
- The New Mexico Minority Based Community Clinical Oncology Program (NM MBCCOP) allows practicing oncologists who serve large minority populations to participate in National Cancer Institute (NCI)-sponsored clinical trials. Since 2000, NM MBCCOP has been funded by the NCI to provide access to federally funded cancer clinical trials. The New Mexico program is headed by Dr. Claire Verschraegen, a medical oncologist at the UNM Cancer Center.

Currently in Albuquerque the NM MBCCOP, with federal funds, and NMCCA, with private sector funding, provide the infrastructure for cancer clinical trials to physicians and health care systems in the Rio Grande corridor. The services include activation of clinical trials, ongoing regulatory oversight, a centralized web database, contracting and budgeting, protocol compliance, and ongoing education. These services allow physicians and health care systems to participate in clinical trials with minimum impact on their staff resources.

NM MBCCOP and NMCCA are working with the Education Network to Advance Cancer Clinical Trials (ENACCT), a national group that works to educate the general public, primary

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care physicians and cancer specialists about clinical trials, on an NIH grant to obtain funding to implement community education for the public, primary care physicians and oncologists on cancer clinical trials.

In October 2010, NMCCA and NM MBCCOP, with the support of Senator Jennings and Representative Gardner, will pilot the model proposed in the NIH grant in Roswell to engage the medical community in clinical trials. If successful, and if funding is obtained, the approach could be implemented statewide with the leadership of the members of the Health and Human Services Committee.

I would be happy to provide you with any additional information you may need, and to meet with you to discuss New Mexicans' access to participation in cancer clinical trials.

Sincerely,

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Alfredo Vigil, MD Secretary