

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

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Ms. Barbara Gordon
Executive Director
Interstitial Cystitis Association
100 Park Avenue, Suite 108A
Rockville, MD 20850

Mr. Mike Hennenfent
President
Prostatitis Foundation
1063 30th Street, Box 8
Smithshire, IL 61478

Dear Ms. Gordon and Mr. Hennenfent:

Thank you for your letter of June 20, 2009. I appreciate your continued interest in the progress of the NIDDK Interstitial Cystitis (IC/PBS) and Chronic Prostatitis (CP/CPPS) research programs, respectively. I have discussed your concerns about NIDDK's future plans for research in these areas with my scientific staff, and would like to respond to them here.

Currently, much of the research in the three areas you cite – epidemiological studies, basic science, and biomarker studies – is being conducted or planned for in the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network. First, the centerpiece of the MAPP is the Epidemiology/Phenotyping project. A major feature of this project, which is expected to start enrolling participants in early fall 2009, is the development and validation of an instrument that can be used to screen and categorize men and women who have chronic pelvic pain and urologic/bladder symptoms. Several life factors, including the effect of the symptoms on quality of life, will be evaluated in the enrolled participants. There are also plans to study subgroups of participants for mechanisms that underlie the chronic pelvic pain. We envision that this investment in careful phenotyping of participants would be leveraged to develop and validate effective survey tools for larger epidemiological studies, such as determining prevalence of chronic prostatitis in men. Development and validation studies may be conducted either within the MAPP – for example, through the Pilot and Feasibility program – or through other mechanisms.

The MAPP Research Network is also conducting basic research. Studies to help determine the mechanism(s) underlying IC/PBS and CP/CPPS, as well as to identify and evaluate biomarkers of the diseases, are a crucial aspect of this research. MAPP scientists will use sample from the participants enrolled in the epidemiology/phenotyping project, as well as from participants from their own institutions/clinics, to perform these studies. We believe that having the clinical assessment (phenotyping) and biomarker discovery and validation in the same study group will

be a very powerful approach to identifying and developing tools for use in future clinical studies and trials.

The neuroimaging study from Northwestern that you cite in your letter is part of another component of the MAPP Research Network, the Neuroimaging project. This project will be studying the using of Neuroimaging/functional MRI to aid in the further understanding of IC/PBS, CP/CPPS, and related disorders. We are currently planning to hold a conference in early 2010 on the role of Neuroimaging/functional MRI in Chronic Pelvic Pain and Associated Disorders. This is being arranged as part of the MAPP Research Network education program. We will also have at the conference, as we have mentioned earlier, updates on our progress in IC/PBS and CP/CPPS research in other areas.

Complementing efforts by the MAPP investigators, there is currently in place a mechanism for persons to apply for funding for basic and clinical studies that are related to all of the MAPP projects. This is the reissue of a Program Announcement, Ancillary Studies to Major Ongoing NIDDK and NHLBI Clinical Research Studies (R01) (<http://grants.nih.gov/grants/guide/pa-files/PAR-07-024.html>). The MAPP Research Network and its individual projects fall under the scope of this PAR. NIDDK will also continue to fund scientifically meritorious investigator-initiated research on the normal bladder and disorders of the bladder, and on mechanisms underpinning IC/PBS, CP/CPPS, and other urologic conditions.

Finally, I am also pleased to let you know that we are planning to include updated information on the burden of IC/PBS and CP/CPPS in the next version of the *Urologic Diseases in America* compendium, which should be released in 2012.

Thank you once again for interest in the NIDDK research programs for IC/PBS and CP/CPPS. I and the Urology Program staff at NIDDK appreciate your concerns regarding research on these burdensome and not well understood diseases. We feel that the MAPP Research Network, in conjunction with other studies such as the RICE (Rand IC Epidemiology project), the BACH (Boston Area Community Health study), and the UDA (Urologic Diseases in America), along with our planned scientific conferences, such as the 2010 Neuroimaging conference, represent strong research investments that should ultimately help improve health for people with or at risk for these diseases. In particular, we hope that the MAPP will discover better screening tools, informative subgroups, pathophysiological mechanisms, and biomarkers that will ultimately lead to better interventional targets and clinical trial designs that can then be tested in future targeted clinical trials in IC/PBS and CP/CPPS. I welcome your continued input on our research activities in these areas.

Sincerely,

Griffin P. Rodgers, M.D., M.A.C.P
Director