

## The Reply



We appreciate Piacentino et al for their interest in our recent article about the health consequences among subjects involved in Gulf oil spill cleanup activities published in *The American Journal of Medicine*.<sup>1</sup> We strongly disagree with their opinion about the findings of our published study. This is a retrospective analysis, which is not based on epidemiological analysis, as Piacentino et al have attempted to argue, using several uncontrollable compounding factors. Unlike prospective clinical studies, retrospective studies are limited to the existing data that have been recorded for reasons other than research.<sup>2</sup> The outcomes generated using retrospective data serve as basis for future prospective studies. In our study, a very well-established standard study design was used to compare the variables (clinical biomarkers) between the 2 groups. The study findings were interpreted and discussed appropriately with existing literature.

The selection of subjects both unexposed and exposed to the oil spill was described clearly in the published article. Because it was a retrospective study, data on lifestyle characteristics, medical history, or employment status were not available for all the subjects included in the study. As argued by Piacentino et al, this study did not use recruitment of subjects to control the variables. As this research was unfunded, it was not feasible to obtain corresponding hematological and liver function data from an appropriately matched external reference group for comparison through the National Health and Nutrition Examination Survey cohort, as was suggested. As was pointed out by Piacentino et al, the additional limitations such as lifestyle exposures, race, ethnicity, chronic medical conditions, medication use, smoking, and alcohol may have played some role, but it is important to know that the subjects in both groups were considered using these variables equally.

Blood and urine samples were collected and stored using standard clinical methods and were subsequently analyzed by independent accredited clinical laboratories. Based on those laboratory findings, physicians routinely diagnose and treat medical conditions. Because samples for both exposed and unexposed groups were collected using these standard

methods for analysis by the nationally accredited laboratories, we believe that the impact on the outcomes is insignificant.

Our study was the first of its kind to report changes in hematological and hepatic functions in the oil spill-exposed subjects. Several investigators have used similar study designs for the evaluation of their subjects exposed to the oil spill in relation to control or unexposed groups.<sup>3-6</sup> We believe that our study is hypothesis driven, with clear objectives, and the conclusions drawn were valid. Thus, the findings of our study form a basis for future prospective clinical studies in this area of research.

In order to further clarify issues raised by Piacentino et al, additional analysis of the clinical data was performed for the oil spill-exposed subjects. In this analysis, we assessed the blood profiles and liver function data of the subjects who participated in the Gulf oil spill cleanup operation and compared them with the standard normal range values. In brief, the results of this analysis indicate that a considerable number of exposed subjects exhibited altered biomarkers above the upper limits of the normalized range.<sup>7</sup> Thus, these results support our earlier published findings. These details can be found in this issue of the *Journal*.

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