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October 15, 1999

Secretary, Department of Health and Human Services  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

Dear Secretary:

I am writing in support of the Roxane Pharmaceuticals' petition to remove the prohibition of LAAM take-home doses from its package labeling. While this effort is being undertaken by the manufacturer, it is timely and has considerable clinical merit.

By way of background, it should be recalled that LAAM's clinical development occurred at a time when there was great anxiety that take-home doses of methadone would pose a major public health hazard by creating a host of primary street methadone addicts. This, as you know, has not proven to be the case after nearly three decades of clinical experience. In that context, however, LAAM's three-times-a-week dosing schedule was originally put forth as an advantage over the daily dosing requirement of methadone and it was said that take-home doses would be unnecessary. However, it was not intended that take-home LAAM doses should be prohibited. Certainly there is no clinical or pharmacological rationale to prevent take-home LAAM when take-home methadone doses are routinely given out.

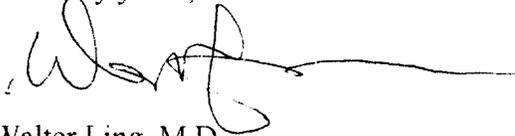
Experience since LAAM's 1993 approval suggests that prohibition of take-home LAAM doses has a significant negative impact on its clinical utility. What data we have on hand, including the study that our group has conducted, suggest that LAAM take-home doses poses no more serious public health issues than methadone. As a practical example, with the current move towards less stringent regulatory constraint on treatment with methadone and LAAM, let us say a patient attends clinic once a week and is given

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medication to take home. This would mean the patient would take home six doses of methadone or two doses of LAAM. Assuming that the public health hazards of LAAM and methadone are comparable pharmacologically, and there is certainly nothing to suggest otherwise, the amount of LAAM needed for take-home dosing alone would appear advantageous over methadone.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Walter Ling', with a long horizontal flourish extending to the right.

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