[TO BE RETYPED ON TAP LETTERHEAD]

July ___, 1995

Mr. Walt Disher
McVey Associates, Inc.
150 Ford Way, Suite 100
Novato, CA 94945

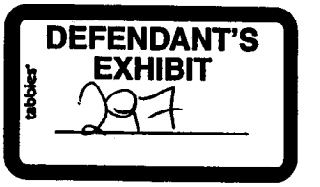
Dear Mr. Disher:

TAP Pharmaceuticals has traditionally supported education to physicians and their office staffs on Medicare and Medicaid reimbursement issues. Reimbursement information is especially important considering the heightened awareness of fraud and abuse laws in recent years. TAP also understands the importance of providers obtaining the maximum reimbursement to which they are legally entitled. We believe that disseminating reimbursement information accurately and in its entirety is crucial in the education process, and are therefore concerned about inaccurate and incomplete information that we have heard you are providing to health care professionals.

Over the past few months, we have had the experience of discussing reimbursement issues with personnel from urology offices who have attended your seminar titled "*Reimbursement & Coding for Urology.*" Based on these discussions, we understand that your interpretation of Federal regulations indicates possible fraudulent billing activity by providers in connection with billing Lupron Depot® 7.5 mg. We believe this is an inaccurate and incomplete interpretation, as detailed below.

There are two main issues I would like to clarify:

1. **Payment for drugs and acquisition costs.**
2. **Discount safe harbors and their reporting requirements.**



1. Payment for drugs and acquisition costs.

Under 42 CFR §405.517(b), "Payment for a drug . . . is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste and spoilage."

This regulation clearly identifies two alternatives for payment. HCFA is well aware of the discrepancies between the two stated alternatives, as detailed in OIG Report No. A-02-01049 Nov. 6, 1992 Subject: Physicians' Costs for Chemotherapy Drugs. HCFA's response to the report was to seek assistance in establishing uniform survey criteria to be used in determining drug payment levels. Efforts thus far have been unsuccessful due to the lack of statistically significant sampling techniques in the survey process.

2. Discount safe harbors and their reporting requirements.

Under 42 CFR §1001.952(h)(1)(iii)(B), "Where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service." Further, 42 CFR §1001.952(h)(1)(iii)(C) states: "The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section."

TAP properly discloses discount information to its buyers on TAP's invoices. It is then the buyers' responsibility to report required discount information to the appropriate state or federal agency. However, neither the Office of Inspector General (OIG) nor the Medicare program have provided any guidance about how a physician should make such a report. There is no space on the paper form HCFA 1500 to do so and, while there is a space on the electronic form (Field 5) in which a physician could note the discount, there are no instructions that this should be done. It is important to

note that this reporting obligation is associated with the amount of the **discount** and has no association with the **charge**.

The preamble section from the Federal Register discusses discounts for charge based providers. The discussion notes that in response to the proposed regulation, many commenters objected to the proposed requirement that charge-based healthcare providers (such as physicians) reduce their charges by the amount of the discount. The OIG replied that it agreed with the discount safe harbor to "delete the requirement that charge based healthcare providers reduce their charges by the full amount of the discount." 56 FR 35952, 35979-80 July 29, 1991.

Further, it must be remembered the safe harbors are only guidelines intended to minimize chances of fraud and abuse law violations. Activities outside of the scope of the safe harbors may be subject to greater government scrutiny, but they are not fraudulent or illegal merely because they do not fall within the narrow confines of the safe harbors.

Mr. Disher, as you can see by the analysis set forth above, the current reimbursement practices for Lupron Depot® 7.5 mg are not fraudulent. In summary, a charged based provider should be reporting a discount amount to a state or federal agency, but there is no adequate mechanism for reporting activity at the present time. There is no limit on the amount to charge for drug, nor does the physician need to reduce his or her charge by the discount. Apparently, the payment and reporting criteria from HCFA need clearer definition pertaining to drug reimbursement for charge based providers.

TAP would appreciate your support by confirming to us in writing that you will eliminate your comments about fraudulent activity associated with Lupron Depot® billing practices. We would prefer to resolve this situation amicably, but if the misrepresentation of Lupron Depot® billing practices continues, TAP will need to refer this situation to legal counsel for further action.

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Thank you for your cooperation. If you would like to discuss this matter in further detail, please contact me directly.

Sincerely,

Gina G. Borkowski

cc: Mark Haberberger, Senior Attorney, Abbott Laboratories
Don Meek, Director Sales Operations TAP Pharm.
Terry L. McVey, President McVey Associates, Inc.