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TO: MEMBERS OF THE LONG ISLAND JEWISH ORGANIZED MEDICAL STAFF

Pfizer attempted to create an interesting program for its Medicare beneficiaries as it related to the drug tafamidis produced by Pfizer. Under normal circumstances the co-pay by a person using the drug and having Medicare Part D coverage would be \$13,000 annually.

Pfizer determined that a party who had no other co-pay Medicare assistance would be confronted with financial difficulties and thus Pfizer authored a plan whereby a Direct Copay Assistance Program would be established with a patient paying \$35 month out-of-pocket to receive the drug with Pfizer absorbing the balance. Pfizer would agree not to use its program to solicit new patients.

The company then asked HHS for an opinion concerning whether or not the Federal Anti-Kickback Statute would prevent the realization of the program. HHS determined that the conduct would be prohibited as it would provide Remuneration in the nature of a valuable subsidy cards and thus induce Patients to purchase the product. Pfizer appealed the finding to the federal Courts in Manhattan.

Pfizer argued that there was no corrupt intent on its part but the court held that no corrupt intent need be established to trigger the effects of the Anti- Kickback law-

the kickback stood on its own regardless of the intent of the parties.

The court also found that the language in the statute of a remuneration to induce did not necessarily refer to corrupt behavior- it was a word neutral as to the quality of the intent in question. Finally, Pfizer argued that the statute speaks of “willful” conduct and thus it implies corruption or Improper influence. Not so, the Court ruled. It was possible that Congress intended not to punish one whose conduct was inadvertent, although improper. Beneficial activities may not be criminal but may not be permitted.

Respectfully submitted.

Schaum Law