

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10259

Pg. 34

Plant Deficiencies

- President is both production and quality control director.
- No double-checking of weighing and measuring.
- Inadequate control over raw material.
- No master formula or batch production records.
- Single lot number for multiple batches.
- Theoretical yields and actual yields are not reconciled.
- No stability studies
- Inadequate laboratory facilities and testing."

Pg. 41

"We must not become over zealous in our aims for cost containment that we jeopardize the health and welfare of the patient by supplying the medical profession with substandard supplies and equipment or furnishing the patient with sub-standard or non-equivalent drug products. Let us not forsake the patient for the sake of the price."

Pg. 43

V.F.W. newly elected Commander-in-chief
Joseph L. Vicities - address - Dallas, 1971 (2)

"The Defense Department has been testing products from small drug companies that are not well-known. The Department of Defense is rejecting approximately 45% of the drugs and medicines it tests before making purchases."

Inspectors from the department have uncovered substandard sanitary conditions and a general absence of even rudimentary quality control in a number of small, back-alley drug manufacturing plants, some of which have been set up by fast buck operators.

The 45% rejection figure applies to drugs actually tested. The products of reputable research-oriented companies are not tested regularly because these companies have proven high standards."

- (1) Presented to 1973 Symposium "Assuring Quality in Health Care Focusing on Professional Standards Review Organizations."
- (2) Presented at the Veterans of Foreign Wars Convention - Statler Hilton Hotel, Dallas, 1971