

University of New England
College of Pharmacy
Core for Drug Analysis and Development

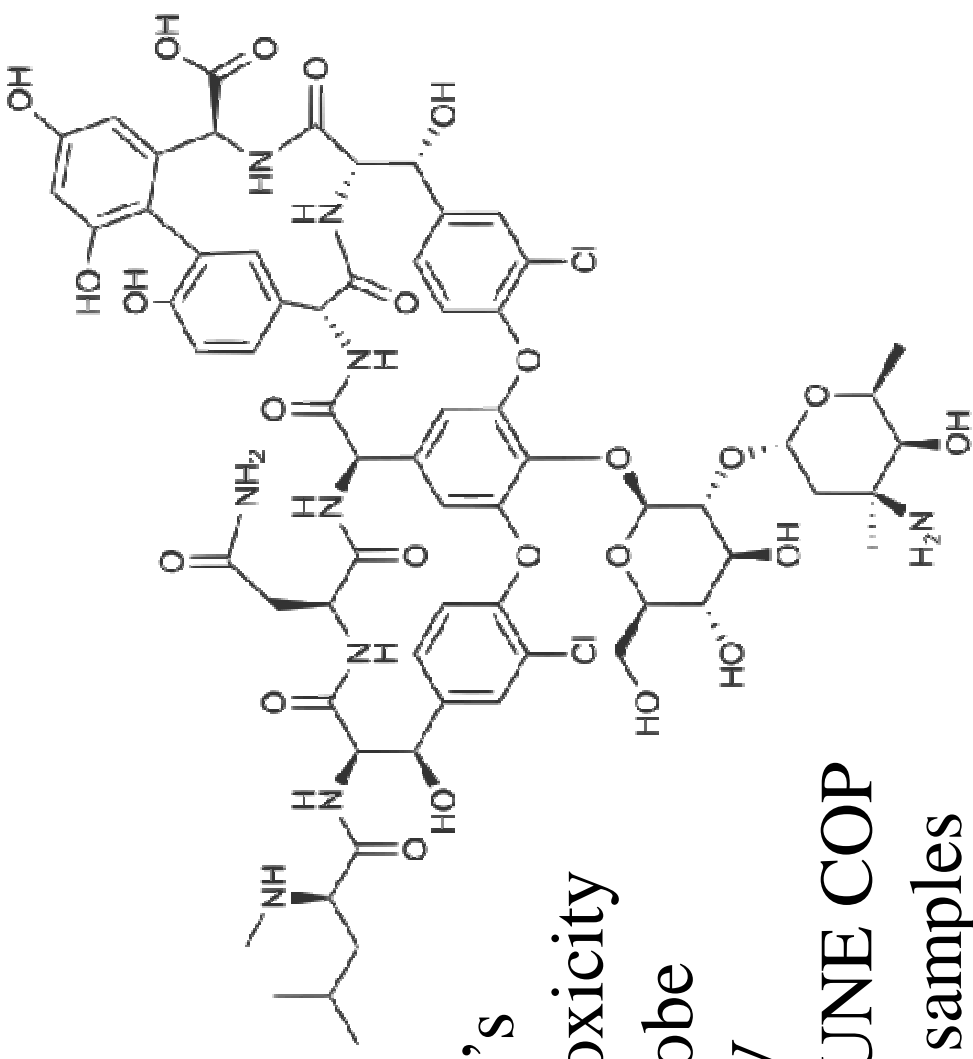
Funded by the Maine Technology Institute

- MTAF 1016 - \$4 million
- CIP 122 - \$480,000

2010 International Symposium on Safe Medicine

John V. Schloss

Vancomycin: Antibiotic of 'Last Resort'

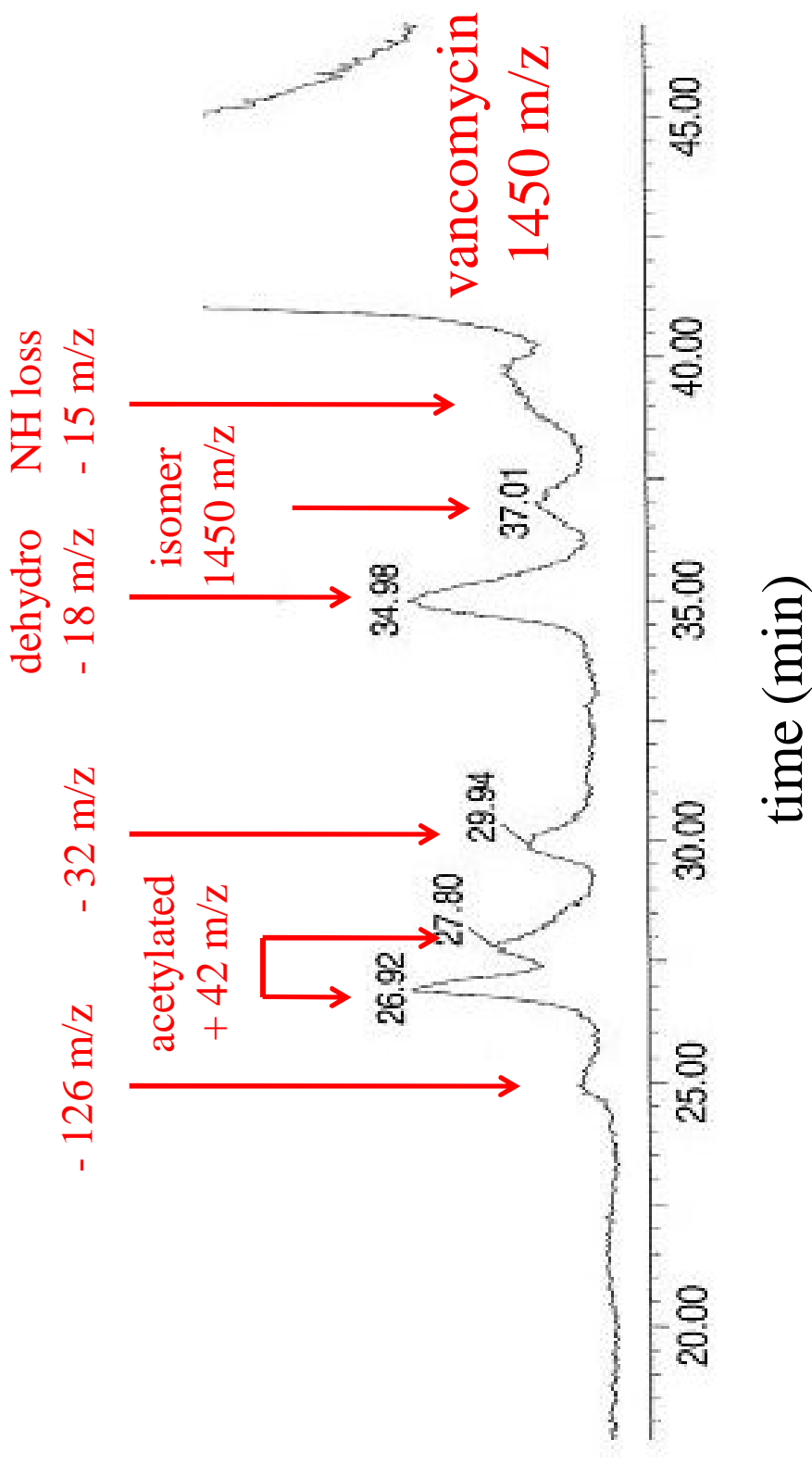


- Introduced in 1950's
- History of nephrotoxicity
- Purified from microbe
- Administered by IV
- Emily Dornblaser UNE COP submitted hospital samples

Comparison of Vancomycin Preparations

Manufacturer	Total Impurities	Major Impurity
USP (standard)	1.5 %	0.58 %
Akorn	2.3 %	1.2 %
APP Pharma	3.4 %	1.2 %
APP Pharma	3.4 %	1.2 %
Hospira	5.0 %	1.5 %
Hospira	5.4 %	1.6 %

Identification of Vancomycin Contaminants



Data collected by Lisa Harding and David Barlow

‘Fortified’ Herbal Medicines

A Source of Stealth Pharmaceuticals

- Herbal preparations from China and India affected
- Jia Yi Jian “100% Herbal” seized by UK authorities
- Malaysian government now requires analysis
- Most common is sildenafil (Viagra) in ED products
- Contaminants include commercial drugs and analogs
- Analogs have not been tested for safety or efficacy
- You don’t find what you don’t look for

Published Reports of Stealth Pharmaceuticals

- Chinese products adulteration incidence 2/7 to 28/81
- Indian ayurvedic had only 1/85 products adulterated
- Contaminants include: sildenafil, tadalafil, homosildenafil, acetildenafil, hydroxyhomosildenafil, dimethylacetildenafil, sibutramine, famotidine, ibuprofen, promethazine, diazepam, nifedipine, captopril, amoxicillin, dextromethorphan, glibenclamide, *N*-nitrosofenfluramine, vardenafil, and piperidenafil

Göker et al. (2010) Turk J Chem 34:157-163; Lim et al. (2009) Radiology 250:193-201; Lin et al. (2006) J Food Drug Anal 14:260-264; Oh et al. (2006) J Tox Environ Health, Part A, 69:1951-1958; Poon et al. (2007) Hong Kong Med J 13:359-363; Singh (2009) Trends Anal Chem 28:13-28; Fleshner et al. (2005) J Urol 174:636-641; Liang et al. (2006) J Pharm Biomed Anal 40:305-311; Savaliya et al. (2010) J Pharm Biomed Anal 52:406-409.

Counterfeit Drugs: The Ghana Experience

- Solid dosage forms easy to counterfeit
- WHO estimates up to 50% counterfeits in Africa
- 2010 USP Medicine Quality (PQM) reports that 14/17 of artesunate tablets collected in Kumasi, Ghana were counterfeit
- 2009 Jennifer Morton of UNE Ghana Health Mission to Sekondi and Takoradi: all samples collected authenticated by LC-MS/MS and HPLC for drug identity and potency
- 2010 Steven Sutton on-site analysis by hand-held infra-red analysis (Polychromix Phazir)