Gundersen Lutheran

May 15, 2003

Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852 Pulmonary Sérvices

Ernesto Brauer, M.D.
Brian M. Hagan, M.D.
Alan D. Pratt, M.D.
Gregory P. Thompson, M.D.
Daren G. Tobert, M.D.
Edward R. Winga, M.D.

Dear Sirs:

I reviewed with great interest the article describing the FDA wanting to require bar codes on the packages of prescription drugs. I have been interested in this issue for many years now. I congratulate you in taking a proactive approach to simplify and make the use of medications safer.

In the past, I have tried to contact the pharmaceutical industry with my idea of using bar codes but this unfortunately was not productive.

I am a believer that the use of bar codes in other industries has been quite successful, like in the food industry. Supermarkets and food warehouses have much more information about tomato paste than what we have knowledge of medications like Digoxin in patients in the United States.

I believe that we should promote the use of bar codes not only in the inpatient medication management, but this should be across the board. I believe that this would simplify the management of medications in the outpatient world.

The use of bar codes could simplify sampling in controlling inventory of samples and distributions of samples to patients.

The pharmaceutical industry could support the software and hardware required to maintain databases on samples and use this to e-mail the pharmaceutical reps when one's inventory is small as defined by previous rules.

Good data could be available for physicians and pharmaceutical industry with protection of the patient's identity.

The prescribing of medications from pharmacies if the bar codes would be in the medications' labels would be made quite easily if the patient would travel from one state to the other.

Large databases controlled by the FDA or regulated by the FDA would provide us with accurate information on medication use and safety.

02N-0204

CYZ

Food and Drug Administration Page 2 May 15, 2003

I would be more than glad to explain my ideas in the future if anybody is interested.

Sincerely,

Ernesto Brauer, M.D.

CC: KevinGlaunert GlaxoSmithKline 607 Guenther Court Onalaska, WI 54650

> Chris Kuchma 1901 North Roselle Road, Suite 500 Schaumburg, IL 60195

Jim Rollins 405 Viking Road Mt. Horeb, WI 53572

Ross Metzler Fax # 847-839-2981