GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA

Greater New York Hospital Association
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Kenneth E. Raske, President

June
Ten
2003

Dr. Mark McClellan
Commissioner
United States Food and Drug Administration
c/o Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner McClellan:

The Greater New York Hospital Association (GNYHA) is a trade association founded in 1904 and comprising nearly 220 not-for-profit hospitals and continuing care facilities, both voluntary and public, in the metropolitan New York area. GNYHA agrees with the intent and terms of the implementation of the proposed bar code label rule, however, we also believe that in order for the final bar code rule to be successful, it will be important for pharmaceutical manufacturers to maintain unit-dose packaging of prescription and OTC medications. Comments regarding the March 14, 2003 proposed rule, **Bar Code Label Requirement for Human Drug Products and Blood**, Docket No. 02N-0204, RIN 0910-AC26 are listed below:

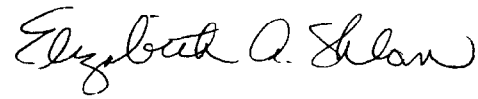
- GNYHA agrees that the bar code should be the responsibility of manufacturers, repackers, relablelers, and private label distributors of prescription drug products and OTC drug products.
- GNYHA agrees that the bar code label requirement should include all prescription drug products, OTC drug products used within a hospital or "institutional setting", and blood products. We also would prefer to have vaccines included in the bar code rule to reduce medication errors associated with their administration. If adding medical devices to the bar code rule would slow down the process of the bar code rule for medications and blood products, then we agree that action on medical devices should be deferred until a later time.
- GNYHA agrees that the FDA should require pharmaceutical manufacturers to apply bar codes to the labels of oral and liquid medications down to the unit-dose size, but GNYHA would also like the FDA to require that manufacturers continue to make all prescription and OTC medications used in hospitals or institutional settings available in unit-dose packages. One of the concerns of GNYHA pharmacy members is that they are seeing fewer medications being made available in unit-dose packaging, and that with the advent of the bar code label requirements; many manufacturers will use this as an opportunity to completely eliminate unit-dose packaging of their medications. Unit-dose packaging of

medications is essential to patient safety and is included in the medication safety practices recommended by the Institute of Medicine, the American Society of Health-System Pharmacists, the Joint Commission on Accreditation of Healthcare Institutions, the National Patient Safety Partnership and the Massachusetts Coalition for the Prevention of Medical Errors. Without commercially available unit-dose packaging, hospitals are forced to deliver bulk bottles of medication to the nursing unit or re-package the bulk medications into unit-dose containers. An average size hospital pharmacy dispenses hundreds of thousands of doses of medications per year and re-packaging these medications into unit-dose containers would put an extreme hardship on most hospital pharmacists and also introduce a new source of error. A March 2002 survey by the Institute for Safe Medication Practices noted that an error rate of 1-10% can be seen when hospital pharmacy departments re-package medications. We would like the FDA to take action to prevent this by requiring pharmaceutical companies to provide medications in unit-dose packaging.

- GNYHA agrees that the bar code should contain, at a minimum, the drug's NDC number and be part of the drug label. We recommend that the FDA also phase-in a requirement to add the lot number and expiration date to the bar code. Monitoring expiration dates on medications is a time-consuming task for both pharmacists and nurses and including this information in the bar code would free up valuable time for healthcare professionals to focus on other areas of medication safety.
- GNYHA agrees that a 3-year period for implementation of the bar code rule is appropriate for pharmaceutical manufacturers and allows them sufficient time to make the bar code labeling available

Thank you for providing us with an opportunity to comment on the proposed rule for Bar Code Label Requirements for Human Drug Products and Blood. If you have any questions about our comments, please don't hesitate to contact us at (212) 506-5448 or shlom@gnyha.org.

Sincerely,



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Senior Vice President
Pharmacy Services

cc: GNYHA Chief Executive Officers
GNYHA Medication Errors Workgroup