MEMORANDUM OF MEETING

between the Food and Drug Administration 2 '02 '13 P3:10
and the National Alliance for Health Information Technology

October 9, 2002
Parklawn Building
Rockville, Maryland

Attendees:

NAHIT
John Combes, American Hospital Association
Kasey Thompson, American Society of Health-Systems Pharmacists
Jill Shamas, Eli Lilly & Co.
Matthew Williams, Premier, Inc.

FDA
Margaret M. Dotzel, Associate Commissioner for Policy
Thomas McGinnis, Office of Policy, Planning, and Legislation
Philip L. Chao, Office of Policy, Planning, and Legislation
Nancy C. Gieser, Office of Policy, Planning and Legislation
Peter Beckerman, Office of the Chief Counsel
Erica Keys, Office of the Chief Counsel
Paul Seligman, Center for Drug Evaluation and Research
Jerry Phillips, Center for Drug Evaluation and Research
Mary Gross, Center for Drug Evaluation and Research

The NAHIT representatives indicated that only 1% of hospitals (excluding government hospitals) currently do scanning at the bedside. The representatives said that NAHIT's members support FDA's bar coding effort and that there is a need to require bar codes on packaged drugs. The NAHIT representatives also indicated that:

- Two hospital groups (Premier and VHA) are already installing bar code scanning systems.
- FDA should require new approvals to have bar codes rather than impose label changes after approval.
- The NAHIT members believe a 3 year implementation period is appropriate. This period reflects the views of the member manufacturers. A 5 year implementation period would be appropriate for inclusion of lot number and expiration date information.
- All OTC drug products should be covered under the rule, although some object to requiring bar codes on all OTC drug products because some OTC drugs present little risk.

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- NCCMERP will issue a report on the use of prescription drugs outside hospitals. This may suggest that bar codes on prescription drugs could play a role outside the institutional setting.

The participants also discussed emerging technologies, such as radio frequency chips, and how bar codes might "leverage" other database uses at the pharmacy, at personnel operations, etc. The NAHIT representatives indicated that a bar code rule is needed because there is no industry leader or single platform or standard, so a bar code rule would deal with the industry fragmentation problem.

The NAHIT representatives also indicated that rural hospitals, due to their economic constraints, might not invest in bar code systems, but would also dispense fewer drugs compared to larger hospitals. For small hospitals, procedural changes, such as a greater emphasis on human intervention, might be employed.

The NAHIT representatives also discussed computerized physician order entry and indicated that it exists in approximately 4.5% of hospitals.

The NAHIT representatives also indicated that:

- Bar codes would help with patient care research because one would be able to track or monitor drug use in hospitals.
- Symbologies should be appropriate to package size and flexibility. They also indicated that they would prefer linear scanning devices now rather than optical scanners because of cost concerns.
- While some vendors, such as McKesson, currently require bar coding, the responsibility should be with the manufacturer.
- A bar code requirement could be applied to all new products after a final rule becomes effective; a 3-year implementation period could be applied to products already marketed at the time of a final rule.

National Alliance for Health Information Technology (NAHIT) Recommendations for the FDA in Issuing the Proposed Rule on Bar Coding for Human Drug Products

Introduction: As a result of the FDA's July 26th public meeting on bar coding several issues requiring additional clarification before issuing a proposed rule on bar code labeling were identified. Among these were what information should be included in the bar code including the timeline for its implementation and what symbology should be employed for the standard bar code. NAHIT has considered these questions and is prepared to offer to the FDA its consensus recommendations.

NAHIT recognizes that the implementation of a final rule on bar code labeling of human drug products will take cooperation and effort among the multiple stakeholders in the medication-use process. Manufactures, supply chain organizations, information technology firms and providers, as participants in NAHIT, are committed to working together collaboratively to ensure the smooth implementation of a final rule. NAHIT also recognizes the critical role played by the FDA in the implementation of the final bar code rule. In light of that role, NAHIT recommends that any guidance language written by the FDA be clear and unambiguous, giving direction to the industry on what is required to meet these new labeling standards. NAHIT recommends that this guidance be issued in an expeditious manner, so our industry can immediately begin the extensive and complex implementation required. In formulating the requirements for the bar code, the FDA should make sure that the bar code does not detract from, or impinge on, the human readable portion of the label, which could then lead to further identification errors. Finally, to attain the timeliest compliance to the new requirements, the FDA should process new labeling applications, which include the bar code without any undue delay and explore improved processes to speed up the review and approval process. By working together the FDA and industry can promote this important step for increased patient safety and proved improved healthcare outcomes for consumers.

The following represents the consensus recommendations of NAHIT:

Bar Code Content and Timeline: NAHIT recommends that the FDA proposed rule require that the NDC number be included in the bar code label for all human drug products, and that this labeling become mandatory for 1) new drug product applications two months after the effective date of the final rule and 2) existing drug labels as soon as practical but in no instance later than three years after the effective date of the final rule.

Lot Number and Expiration Date should be included in the bar code for all package sizes, down to the unit-dose level, within 5 years from the date of the final FDA rule. If the technology is not available in 5 years to print the Lot Number and Expiration Date, the regulatory language should state that manufacturers will provide FDA with an unbiased, objective assessment of the current state of technology, and valid reasons why the

printing of Lot Number and Expiration Date in bar codes is not feasible. The FDA should then be willing to provide pharmaceutical manufacturers a reasonable extension for the required inclusion of Lot Number and Expiration Date. This could be achieved by asking the FDA to commit to holding a hearing 2 years before the 5-year deadline to affirm the feasibility of adding the Expiration Date and Lot Number to bar codes.

This approach would provide patients, practitioners, and institutions the assurance that, if the technology is available, then bar codes on all package sizes will include Lot Number and Expiration Date within 5 years from the date of the final FDA rule. And, just as important, this approach gives an "out" for pharmaceutical manufacturers if the technology has not advanced enough to include the Lot Number and Expiration Date along with the National Drug Code in bar codes.

NAHIT is aware of the burden for pharmaceutical manufacturers to relabel existing product lines with bar codes and recommends the longer time for compliance so that this burden will not be an obstacle to the continued production of unit dose packaging and other drug products. However, NAHIT encourages the expeditious relabeling of existing drug products with bar codes as soon as feasible. It is expected that manufacturers will immediately begin the process of relabeling much of their product line in order to insure that all lines are in compliance well before the three-year requirement.

The inclusion of the lot number and expiration date in the bar code remains a priority for NAHIT, however; technical obstacles to their inclusion would delay the implementation of the bar code with the NDC number which could then have deleterious effect on patient safety. As outlined above, NAHIT stands ready to work with the FDA and the pharmaceutical industry to adopt standards and processes to accomplish the goal of human drug products labeled with a bar code that include the NDC, lot number and expiration date within five years of the adoption of the final rule.

<u>Symbology:</u> The choices for the appropriate symbology for the bar code is a critical element of the proposed rule and should be governed by the following principles: **1) NAHIT recommends that only existing symbologies utilized in healthcare with the capacity to include the NDC be used for the bar coded label and 2) only symbologies appropriate to the pharmaceutical packaging size and capable of being printed and scanned by existing and readily available commercial printing and scanning technology should be selected.** These principles would allow flexibility to pharmaceutical manufacturers while providing for a level of standardization for the users of the scanning devices without significantly increasing their costs.

Given these principles, **NAHIT further recommends that no single symbology for the bar code be defined in the FDA proposed rule and that symbologies ultimately approved by the FDA for the bar code label follow the above set of principles.**