HCPC
HEALTHCARE COMPLIANCE PACKAGING COUNCIL

June 12, 2003

Dockets Management Branch
(HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: FDA REQUEST FOR COMMENT, PROPOSED RULE, "BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD" 68 FR 50, FDA DOCKET NUMBER 02N-0204

Dear Dockets Manager:

I am writing on behalf of the Healthcare Compliance Packaging Council (HCPC) in response to the notice of proposed rulemaking (NPRM) entitled "Bar Code Label Requirements for Human Drug Products and Blood" that appears in the March 14, 2003 edition of the *Federal Register*.

The HCPC is a not-for-profit trade association established in 1990 to promote the many benefits of unit dose blister and strip packaging. HCPC member companies include manufacturers of pharmaceutical-grade film, foil, and paperboard as well as manufacturers of machinery used to create unit dose blister and strip packaging. HCPC member companies also include a number of FDA-registered contract packaging firms that provide specialty packaging services to pharmaceutical manufacturers, and an FDA-registered repackaging operation that, among other things, packages drug products for use in hospitals and other healthcare facilities throughout the United States.

The HCPC is the recognized authority on issues associated with unit dose packaging, and has been an active participant in the bar code debate. The HCPC presented testimony and

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written comments (copies attached) on this issue during FDA's public hearing on July 26, 2002 and participates on the United States Pharmacopeial's Committee on Drug Repackaging.

Overall, the HCPC supports FDA efforts to require use of bar code technology to ensure that patients treated in healthcare facilities receive the right drug, in the prescribed amount, through the correct form of administration, at the correct time. As demonstrated through reams of research, healthcare industry practice, and recommendations from numerous sources, the only proven way to achieve this goal is through the use of bar code technology tied to unit dose packaging so that scanning can be done throughout the healthcare facility's entire distribution chain (i.e., from the moment the drug product enters the pharmacy until the moment it is given to the patient).

With this in mind, HCPC's primary concern with FDA's proposed rule is that it does not go far enough to ensure that a bar code will remain with the drug product during the entire distribution process.

Specifically, as proposed, ***the rule would not require that bar codes be placed on each dosage unit of drug product intended to be dispensed in healthcare facilities,*** the result being that many facilities will have little or no incentive to invest in technologies needed to perform the final step needed to prevent medication error – bedside scanning of the medication before it is given to the patient.

The HCPC strongly urges FDA, therefore, to alter the rule such that a bar code would have to be printed on each dosage unit of any prescription (Rx) or over-the-counter (OTC) product intended for use in in-patient settings before the product enters the healthcare facility's pharmacy. Following are our more detailed comments on this issue:

FDA Proposal

As published in the March 14, 2003 edition of the *Federal Register,* FDA notes that publication of the Institute of Medicine's (IoM) report entitled "To Err is Human: Building a Safer Health System" in 1999 was a primary action triggering this rulemaking effort. Specifically, FDA points out the IoM study documents an unacceptably high number of deaths associated with in-patient medication errors, and the Agency notes that the IoM report "...stated that deaths due to medication errors are often preventable and cited bar codes as one way to prevent them (Ref. 1 at pp. 37, 175, 188, 189, 195-196)" (68 FR 50, page 12500).

With all due respect, the HCPC notes that the IoM report cited by FDA actually states that bar codes ***used in conjunction with unit dose packaging – not bar codes alone*** – is a means of preventing medication errors.

Specifically, on pages 166-167 of its 1999 report, the IoM recommends that: "If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy." The report justifies this recommendation by noting that "Unit dosing...reduces handling as well as the chance of calculation and mixing errors."

But the IoM also sounded an ominous alert in this section of the report by pointing out that "Unit dosing was a major systems change that significantly reduced dosing errors when it was introduced more than 20 years ago...unfortunately some hospitals have recently returned to bulk dosing [as a cost-cutting measure], which means that an increase in dosing errors is bound to occur."

The need for use of bar codes in conjunction with unit dose packaging was also repeatedly cited during FDA's July 26 public hearing.

In testimony presented by the Federation of American Hospitals, for instance, FAH stated that "bar coded medication administration system(s)....should work in the following manner: 1) Each medication ***should be unit-dosed***. 2) Each ***unit dose medication*** should be labeled with human readable information..." (Emphasis added). Furthermore, in its July 26, 2002 recommendations to FDA, the FAH said that "Each dose" of drug product should be accompanied by a bar code.

Similarly, during his statement last year, Michael R. Cohen, RPh, MS, ScD, President of the Institute for Safe Medication Practices noted, that "...an important component of the [needed] regulation ***must be that manufacturers provide unit dose packaging of medications*** with a bar code" (Emphasis added).

Kasey Thompson, Pharm. D., Director of the Center for Patient Safety at the American Society of Health-System Pharmacists (ASHSP) also advocated use of bar code technology in conjunction with unit dose packaging during the July 26, 2002 hearing, and even drew a distinction between the need for unit dose formats over unit-of-use formats. Indeed, in his testimony, Mr. Thompson:

- Called on FDA to "...mandate that standardized machine-readable coding be placed on all manufacturers' single-unit drug packaging..."
- Told the Agency that "For bar coding to be effective in hospitals and health systems, products in unit-dose packages ***must*** be made available by pharmaceutical manufactures" (Emphasis in original).
- Recommended that "Bar codes...be required on all pharmaceutical product packages ***down to the unit-dose – single unit level***" (Emphasis in original). And

- Noted that "Institutions need incentives to use this important patient safety enhancing technology. This can be achieved through an FDA requirement and commitment by manufacturers to do what's right for patients – include bar codes on all product packages, and make all products available in unit-dose form."

In FDA's March 14, 2003 NPRM, the HCPC also notes that each of the examples of industry practice cited by FDA for achieving significant reductions in medication errors (68 FR 50, page 12502) involved use of bar codes *and* unit dose packaging.

Yet despite all of these recommendations, endorsements, and documented successes, FDA's NPRM would not require use of unit dose packaging in conjunction with bar code technology. All that would be required of manufacturers under the rule, as proposed, is to ensure that a bar code accompany whatever count package is intended for use in healthcare facilities. Indeed, as the HCPC reads the NPRM, manufacturers would be free to ship thousands of dosage units to healthcare facilities in a single container, as long as it contained a bar code on its labeling.

Considering the current paradigm of bulk distribution of drug products by pharmaceutical manufacturers in the United States, and the documented trend over the past 5-7 years of pharmaceutical manufacturers actually *decreasing* the number of products available in hospital unit dose formats,[1] the HCPC asserts that the NPRM, as proposed, would do nothing to encourage manufacturers to adopt unit dose formats. This, in turn, calls into question FDA's assumed benefits of the proposed rule cited in the NPRM – although the benefits for outpatient dispensing cited in the NPRM would still likely hold.

Specifically, as outlined under the section of the NPRM entitled "How Would Bar Coding Help Prevent Medication Errors," (68 FR 50, pages 12501-12502) FDA provides a model that – if followed – is expected to yield an "annualized societal benefit" of $3.9 billion due to reduction of adverse drug events in hospital settings (68 FR 50, page 12524). In this model, FDA notes that:

> In hospitals, health-care professionals, such as pharmacists and nurses, would use bar code scanners (also called bar code readers) to read the bar code on the drug before dispensing the drug to the patient and ***use bar code scanners to read a bar coded wrist band on the patient before giving the drug to the patient.*** In an outpatient setting, the health care professional (such as a pharmacist) could scan the bar code on the drug and compare the scanned information against the patient's electronic prescription information before giving the drug to the patient. (68 FR 50, page 12502, emphasis added).

[1] Please see Michael R. Cohen's testimony of July 26, 2002 as but one reference to this phenomenon. Specifically, Dr. Cohen reported that "...we are experiencing a decrease of the availability of unit dose packaging by many manufacturers."

The HCPC questions how this model would work if the hospital pharmacy receives drug product from a manufacturer in a bulk container. While it is true that the pharmacist would be able to scan a bar code on the bulk container *in the pharmacy* if the NPRM were adopted, the product must be removed from its original container to be dispensed to the patient. At this point the product becomes separated from its bar code, precluding the ability to compare the product *at the bedside* with information "read from a bar coded wrist band on the patient."

If healthcare facilities cannot rely on the manufacturer to provide packaging that can be scanned throughout their entire distribution chains (including the patient's bedside), the HCPC asserts that FDA's model – and the anticipated benefits associated with it – breaks down. To the extent FDA assumes there would be a significant reduction in hospital-based medication errors simply because hospital pharmacists are able to scan the bar code on a bulk container of drug product in the hospital pharmacy, the HCPC urges the Agency to fully detail those assumptions prior to finalizing the proposed rule.

Conclusions

In its March 14, 2003 NPRM, FDA asked for comments on a number of issues related to a proposed bar code requirement. On page 12529 of that NPRM, the Agency requests comment on 12 separate points, none of which relate to the need for bar codes to be used in conjunction with unit dose packaging. While the HCPC has already filed comment with the Agency (copy attached) regarding a number of the issues raised on page 12529 of the NPRM, we assert that – unless the Agency uses this rulemaking as an opportunity to require that Rx and OTC drug products dispensed in hospital settings are packaged in a unit dose format with a bar code by either the manufacturer, an FDA-registered contract packaging firm, or an FDA-registered repackaging operation – these issues are moot.

We urge FDA, therefore, to alter the NPRM to ensure that drug products are received by healthcare facilities in a unit dose format bearing a bar code. Otherwise, we ask that the Agency re-examine the anticipated benefits of this proposed rule, and provide a better analysis of how these benefits would accrue.

On behalf of the Healthcare Compliance Packaging Council, I again thank FDA for the opportunity to file these comments. Please feel free to contact me should you have any questions or need any additional information.

Sincerely,

Peter G. Mayberry
Executive Director

HCPC
HEALTHCARE COMPLIANCE PACKAGING COUNCIL

July 12, 2002

VIA FACSIMILE: 301/443-9664

Mary C. Gross
Office of Drug Safety
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15B-32
Rockville, Maryland 20857

RE: Docket Number 02N-0204 ("Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting")

Dear Ms. Gross:

Attached please find a copy of the brief statement I intend to make on behalf of the Healthcare Compliance Packaging Council (HCPC) during the July 26 FDA public meeting on Bar Code Label Requirements for Human Drug Products. Please contact me should you have any questions or need additional information regarding the attached.

Thank you.

Sincerely,

Peter G. Mayberry
Executive Director

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Statement of:

Peter G. Mayberry
Executive Director
Healthcare Compliance Packaging Council

FDA Public Meeting on Bar Code Label Requirements for Human Drug Products

July 26, 2002

National Institutes of Health
Bethesda, Maryland

Greetings. My name is Peter Mayberry and I am here today on behalf of the Healthcare Compliance Packaging Council. The HCPC is a not-for-profit trade association founded in 1990 to promote the many benefits of unit dose blister and strip packaging. HCPC members include companies involved in the manufacture of pharmaceutical films, foils, and paperboard used in the production of unit dose blister and strip packaging used with prescription drugs, OTC medications, and dietary supplements. HCPC members also include blister packaging machinery manufacturers as well as contract packaging firms and commercial repackaging companies that specialize in providing healthcare products in unit dose formats. For more information about the HCPC, I invite you to visit our website at www.unitdose.org.

Unit dose formats are widely used in hospitals and other in-patient settings as a means of ensuring that the right medications are dispensed to the right patient at the right time and in the right amount, and I am here today to share our views on the questions raised in FDA's June 18 *Federal Register* notice. In the interest of time, however, I will limit my oral comments to the single most important point that the HCPC wishes to address today, and provide a more detailed list of answers to the Agency's questions in the form of written responses appended to this statement.

My primary point today, therefore, is that the HCPC strongly supports FDA efforts to require the use of barcodes for medications dispensed in in-patient settings as a means of reducing hospital medication errors, but we draw your attention to the fact that the Institutes of Medicine (IoM) recommendation on which this effort is largely based also calls for use of unit dose packaging as a critical factor in preventing medication errors.

Specifically, on pages 166-167 of the 1999 report "To Err is Human: Building a Safer Health System," IoM notes that: "If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy." The report justifies this recommendation by noting that "Unit dosing...reduces handling as well as the chance of calculation and mixing errors." But the IoM also sounded an ominous alert in this section of the report by pointing out that "Unit dosing was a major systems change that significantly reduced dosing errors when it was introduced more than 20 years ago...unfortunately some hospitals have recently returned to bulk dosing [as a cost-cutting measure], which means that an increase in dosing errors is bound to occur."

Indeed, in the time since the IoM report was first released, the HCPC has heard a growing number of anecdotal reports that pharmaceutical manufacturers are dropping the number of products offered in hospital unit dose – or HUD – formats. As recently as May 15 of this year, in fact, one pharmaceutical manufacturer noted during the HCPC's National Symposium on Patient Compliance that his company had deleted HUD formats for some 80 percent of their entire drug stock over the past two years.

As FDA considers the need for barcodes as a means of reducing medication errors, therefore, the HCPC strongly urges you to remember that the IoM actually recommends barcodes along with unit dosing – and not barcodes alone – as the best way to address this serious, national health

issue. To that end, the HCPC also urges FDA to consider ways of expanding access to HUD formats, and ensuring that hospitals can easily obtain such formats directly from the manufacturer so that products do not have to be repackaged at the pharmacy level. By doing so, FDA would be fully implementing the IoM recommendations and maximizing safety to the greatest extent possible.

And it is not just the IoM that has recommended unit dosing as a means of reducing medication errors. Included in the groups that have recently called for greater use of unit dosing are the National Patient Safety Partnership, the Joint Commission on Accreditation of Healthcare Organizations, and the American Hospital Association. The Department of Veterans' Affairs has also embraced unit dosing for its healthcare facilities, and it is our understanding that the Centers for Disease Control purchase drugs in unit dose formats when they are available for use in the National Pharmaceutical Stockpile. The HCPC also notes that unit dose formats are routinely used as manufacturers' original packaging throughout most of the other industrialized countries in the world, and we are unaware of any countries where these formats are used that have medication error rates similar to those of the United States.

Based on all of these recommendations, endorsements, and experiences in other countries, it is clearly within the best interests of patient safety throughout the United States for FDA to take immediate steps that will foster greater availability of unit dose formats as original manufacturers' packaging, and the HCPC submits that these efforts should be closely tied to any regulatory considerations that would require use of barcodes.

One way of achieving this goal, in fact, would be for FDA to require that barcodes be provided by the manufacturer ***on each dosage unit*** of product intended for distribution in an in-patient setting. It is the HCPC's understanding that barcoding at the unit dose level for dispensing pharmaceuticals in in-patient settings is already a common practice among commercial repackaging operations and, therefore, this approach should be feasible for universal adoption. If FDA were to adopt such a requirement, therefore, it would simultaneously meet the recommendations of both the IoM and the National Patient Safety Partnership, and also help to reduce the need for pharmacy personnel to repackage drugs.

On behalf of the entire HCPC I thank you for the opportunity to present these views. As I noted at the beginning of my statement, there is a more comprehensive set of responses to the Agency's specific questions attached to this statement. I will be happy to answer any questions you have regarding either my oral comments today or the written responses that are also part of this statement.

HCPC Responses to Questions Raised by FDA in 67 *Federal Register* 117 (June 18, 2002, page 41361)

FDA Docket No. 02N-0204

Appendage to Statement of:

Peter G. Mayberry
Executive Director
Healthcare Compliance Packaging Council

Following are answers from the Healthcare Compliance Packaging Council (HCPC) *in response* to questions raised by the U.S. Food and Drug Administration (FDA) on page 41361 of the *Federal Register* dated June 18, 2002. These responses are an appendage to the statement presented by HCPC Executive Director Peter G. Mayberry during FDA's public meeting on "Barcode Labeling Requirements for Human Drug Products" held July 26, 2002.

General Questions Related to Drugs and Biologics:

1. *Which medical products should carry a barcode? For example, should all prescription and over-the-counter (OTC) drugs be barcoded? Should blood products and vaccines carry a barcode?*

While the HCPC contends that relevant literature points to the benefits of barcoding for all prescription and OTC drug products, it is clear that the greatest current need is for barcodes on prescription products – especially those intended for in-patient dispensing.

Based on findings and recommendations from the Institutes of Medicine (IoM), the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), the American Hospital Association (AHA) and others, it is clear that barcodes facilitate the ability of personnel in in-patient settings to ensure that the right medication is dispensed to the right patient, in the right amount, and at the right time.

As the HCPC understands the issue, however, pharmacy personnel are often required to repackage drug products from bulk formats into those that carry a barcode. And anytime that product is repackaged, errors can be made. The safest system, therefore, would be based on manufacturers' original packaging in unit dose formats that carry barcodes which can be universally read. Such a system would preclude the need to repackage drug products at the pharmacy level, and thereby significantly reduce the opportunity for mistakes to be made.

Similarly, with regard to medications dispensed by commercial pharmacies, patient safety would be enhanced significantly through use of barcodes. For example, if barcodes appear on prescription drugs, an immediate benefit would be the ability for pharmacy personnel to scan multiple products dispensed to the same consumer to ensure against contraindications. Beyond this, barcode requirements could usher in the use of entire systems for commercial dispensing that could rival those used in in-patient settings. For example, if those who prescribe drugs could affix a product barcode to the prescription itself, the dispensing pharmacy would be able to scan that prescription and the product to ensure that the right drug is being dispensed to the right patient in the right amount. But unless Rx drug products carry barcodes, there is little or no incentive for the actual prescriptions to carry such codes either.

In summary, the HCPC believes it is imperative to require use of barcodes for all drug products dispensed in in-patient settings, and urges FDA to mandate the use of barcodes for these products as soon as possible. To the extent that expanding this mandate to drug products dispensed by commercial pharmacies may hinder implementation of a

requirement for in-patient settings, the HCPC encourages FDA to focus on *in-patient* settings first.

2. *What information should be contained in the barcode? What do you consider to be critical barcode information that will reduce medical product errors? If data exists, please provide it for the record. What information would be helpful but not necessarily critical, for reducing medication errors? Provide data.*

The most critical piece of information that should be included on a barcode used for immediate packaging is the NDC number because it is specific to the medication and its dose. Simply stated, without an NDC number, a barcode would be of little or no value. A barcode containing the drug product's NDC number is so important, in fact, that it should be printed on each unit dose of medication.

Beyond the NDC number, there are two other pieces of information that are of primary importance: the product's lot number and expiration date. But while this information is important – especially when product recalls are required – the HCPC contends that it could be printed on either the product's immediate packaging (space permitting) or secondary packaging.

3. *Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific barcode symbology (e.g., reduced space symbology (RSS) and 2-dimensional symbology)? Should we adopt one symbology over another, or should we allow for "machine readable" formats? What are the pros and cons of each approach?*

Unfortunately, the HCPC is not in a position to recommend a specific symbology, but we strongly believe that standardization is critical if the benefits of barcoding are to be realized. Indeed, one of the most often stated reasons given to the HCPC for why barcodes are not more widely used is the lack of standards which has resulted in a multitude of varying proprietary symbologies that cannot be read unless a specific system is in use.

Despite the fact that the HCPC is unable to make a specific recommendation regarding the exact standards that should be used by FDA, we do believe that the standards should be based on the following elements:

* The symbology should be capable of being printed at speeds that accommodate form, fill, and seal machinery.

* The symbology should allow for scanning through all stages of in-patient dispensing, including the patient's bedside.

* At a minimum, the symbology should include the product's NDC number.

* The symbology should allow for scanning by the most economical means possible.

4. *Assuming that we require barcodes on all human drug products, where on the package should the barcodes be placed? Are there benefits to placing barcodes on immediate containers, such as the bottles, tubes, foiled-wrapped tablets, and capsules, found inside prescription or OTC product cartons? Is there a way to distinguish whether certain containers with a barcode will have a more significant effect on preventing errors than others?*

While the HCPC strongly supports FDA efforts to require the use of barcodes for medications dispensed in in-patient settings as a means of reducing hospital medication errors, we note the fact that the Institutes of Medicine (IoM) recommendation on which this effort is largely based also calls for use of unit dose packaging as a critical factor in preventing medication errors.

Specifically, on pages 166-167 of the 1999 report "To Err is Human: Building a Safer Health System," IoM notes that: "If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy." The report justifies this recommendation by noting that "Unit dosing...reduces handling as well as the chance of calculation and mixing errors." But the IoM also sounded an ominous alert in this section of the report by pointing out that "Unit dosing was a major systems change that significantly reduced dosing errors when it was introduced more than 20 years ago...unfortunately some hospitals have recently returned to bulk dosing [as a cost-cutting measure], which means that an increase in dosing errors is bound to occur."

Indeed, in the time since the IoM report was first released, the HCPC has heard a growing number of anecdotal reports that pharmaceutical manufacturers are dropping the number of products offered in hospital unit dose – or HUD – formats. As recently as May 15 of this year, in fact, one pharmaceutical manufacturer noted during the HCPC's National Symposium on Patient Compliance that his company had deleted HUD formats for some 80 percent of their entire drug stock over the past two years.

As FDA considers the need for barcodes as a means of reducing medication errors, therefore, the HCPC strongly urges you to remember that the IoM actually recommends barcodes along with unit dosing – and not barcodes alone – as the best way to address this serious, national health issue. To that end, the HCPC also urges FDA to consider ways of expanding access to HUD formats, and ensuring that hospitals can easily obtain such formats directly from the manufacturer so that products do not have to be repackaged at the pharmacy level. By doing so, FDA would be fully implementing the IoM recommendations and maximizing safety to the greatest extent possible.

And it is not just the IoM that has recommended unit dosing as a means of reducing medication errors. Included in the groups that have recently called for greater use of unit dosing are the National Patient Safety Partnership, the Joint Commission on Accreditation of Healthcare Organizations, and the American Hospital Association. The Department of Veterans' Affairs has also embraced unit dosing for its healthcare facilities, and it is our understanding that the Centers for Disease Control purchase drugs

in unit dose formats when they are available for use in the National Pharmaceutical Stockpile. The HCPC also notes that unit dose formats are routinely used as manufacturers' original packaging throughout most of the other industrialized countries in the world, and we are unaware of any countries where these formats are used that have medication error rates similar to those of the United States.

Based on all of these recommendations, endorsements, and experiences in other countries, it is clearly within the best interests of patient safety throughout the United States for FDA to take immediate steps that will foster greater availability of unit dose formats as original manufacturers' packaging, and the HCPC submits that these efforts should be closely tied to any regulatory considerations that would require use of barcodes.

One way of achieving this goal, in fact, would be for FDA to require that barcodes be provided by the manufacturer ***on each dosage unit*** of product intended for distribution in an in-patient setting. It is the HCPC's understanding that barcoding at the unit dose level for dispensing pharmaceuticals in in-patient settings is already a common practice among commercial repackaging operations and, therefore, this approach should be feasible for universal adoption.

If FDA were to adopt such a requirement, therefore, it would simultaneously meet the recommendations of both the IoM and the National Patient Safety Partnership, and also help to reduce the need for pharmacy personnel to repackage drugs.

5. *What products already contain barcodes? Who (i.e., hospitals, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these barcodes and how? As with all comments, if data exists, please provide it for the record.*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

Medical Device Questions

The HCPC has no position on use of barcodes for medical devices.

General Questions and Economic Impact Questions:

1. *Will barcode printing costs cause you to modify your packaging choices, such as reconsidering the use of blister packages or influencing future package choices? If so, how?*

As previously noted, use of barcodes alone has not been widely endorsed as the means to reduce medication errors. Rather, it is the use of barcodes in conjunction with unit dose packaging, whenever possible, that is needed. To that end, the HCPC strongly urges FDA to mandate use of barcodes at the unit dose level. In addition, considering the

safety ramifications, FDA should consider using its CGMP authority to mandate use of unit dose blister formats, whenever possible, for drug products – especially those intended for in-patient dispensing.

Two other points to consider on this issue are: 1) the cost of requiring use of barcodes for drug products relates directly to the complexity of the required code (i.e., the more complicated the symbology, the higher the cost); and 2) manufacturers' costs can be reduced substantially through outsourcing.

With regard to the first point, the HCPC notes that use of one-dimensional symbologies is not especially costly, and that two-dimensional symbologies should not be prohibitively expensive either. Beyond these relatively simple symbologies, however, costs can become a major, determining factor. To the extent that FDA's concerns are focused more on packaging costs than patient safety, therefore, the Agency should mandate use of either one- or two-dimensional symbologies.

With regard to the second point, the HCPC notes that pharmaceutical manufacturers often cite costs based on the purchase of new packaging and/or printing lines when faced with potential regulations of this sort (e.g., FDA regulations requiring unit dose packaging for products that contain 30 mg or more of iron per dosage unit [see FDA Dockets Nos. 91P-0186 and 93P-0306]). What these arguments fail to consider, however, is that contract packaging firms, FDA-registered repackaging operations, and commercial printers are resources which are readily available to pharmaceutical manufacturing firms, and can be used to outsource functions mandated by FDA at a fraction of the cost. This is the case because contract packagers, FDA-registered repackaging operations, and commercial printers already have the equipment needed to fulfill most any regulatory requirement.

2. *Have you implemented barcode technology in your product line? If so, what elements and symbology are included in the barcode?*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

3. *If you manufacture and barcode products, how do verification requirements for barcodes affect your ability to add barcodes? How much barcode verification is appropriate as part of the quality system?*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

4. *Can barcodes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

5. *What equipment solutions are vendors offering to manufacturers for barcoding or scanning? How quickly can such systems run? What type of packaging line is equipment used for?*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

6. *What is the expected rate of technology acceptance in all health care sectors of machine-readable technologies? What are the major inhibiting factors to the current use of machine readable technologies? What would be the expected benefit of using machine readable technology in the delivery of health care services (including drug products)? What would be the expected benefit of machine readable technology for other potential uses (e.g., reports, recordkeeping, inventory control, formulary setting, etc.)?*

While it is the HCPC's understanding that one or more of our member companies may address this question in individual replies to FDA, as an organization the Council does not believe it can provide meaningful data on this topic.

7. *Assuming a final rule is issued requiring barcoding, when should it become effective? For example, would some industries or products require more time than others to comply with a barcoding requirement? Would a certain compliance time sharply reduce costs of relabeling?*

The HCPC reiterates its view that use of barcodes in conjunction with unit dose packaging is a critical safety issue, and that numerous medication errors occur every day that the current paradigm for pharmaceutical dispensing remains in place. Even though there are disagreements over the exact scope of this national healthcare problem, it is widely acknowledged that medication errors are the most prevalent, preventable threat that patients face when admitted to a hospital or other in-patient facility. Mistakes occur on a daily basis in commercial pharmacies as well. With this in mind, the HCPC urges FDA to act with the greatest possible haste to require that barcodes be used in conjunction with unit dose formats.