

1 implementation of barcoding and wait until a complete  
2 barcode system is together with lot number and  
3 expiration date, I think we have to think about the  
4 patient impact of that, and those patients that are  
5 going to die in the meantime who could possibly have  
6 preventable medication errors just simply by  
7 recognition of an NDC number.

8           So when we think about timelines and we start  
9 to get out to two years and three years and five years,  
10 I think it's pretty obvious and there's very good data  
11 about the number of medication errors. Many of those  
12 are wrong drug, wrong dose. We know about some that  
13 have been highly publicized. Many of those could be  
14 prevented with the system. So I'd like to have you  
15 take that into consideration.

16           Also, it's true that the availability of  
17 barcoding is rapidly changing. So as well as the  
18 utilization of systems within hospitals that can  
19 recognize that information, the '99 study by ASHP --  
20 and I think they said that they're going to have some  
21 new information in a couple months -- I suspect that  
22 that will be very different.

1           But when you think about those who can scan at  
2 the bedside, you have to think about the availability  
3 of the medications to scan. One of our members in  
4 North Dakota is well along this way, but they put a lot  
5 of investment to repackage everything that doesn't come  
6 in. Many hospitals can't do that or don't want to do  
7 that, so they wait for it to be available.

8           In terms of priority for products, I think  
9 it's important, and I personally don't see any  
10 distinction between NDC -- or between over-the-counter,  
11 rather, and prescription items. I think both of those  
12 are important.

13           I think it's important to understand, from a  
14 safety process standpoint, the nurse at the bedside  
15 needs to work with one system, not a manual system for  
16 OTC meds and another system for prescription meds,  
17 because you introduce more potential for med errors and  
18 it could be worse than what we started with.

19           But when we focus on -- and this primarily  
20 also goes to the manufacturers -- think about the types  
21 of medications that are used at the bedside. When you  
22 look at products to barcode, it's not those with the

1 highest sales dollars nor those that cost the most.  
2 It's those that are administered at the bedside where  
3 there could be a benefit from barcoding and recognition  
4 at the bedside.

5 Unit dose medications, ampules, vials, those  
6 kinds of things, certainly not bulk vials that stay in  
7 the pharmacy. There may be some barcoding application,  
8 but again, if you think about the greatest return on  
9 investment, that's going to come from the bedside  
10 aspect of that. Topical tubes, medications that are  
11 dispensed in eyedroppers, and whatnot.

12 And it's interesting to note, with the RSS  
13 technology today, that the barcode scanner -- the  
14 barcode symbol is now capable of being put on an ampule as  
15 small as 2 mls and not compromise the label. So the  
16 technology is there. Abbott is one of the leaders, and  
17 I've got some other companies that are far along in  
18 that stage. But Abbott has put some effort into that  
19 as well.

20 MR. ROBERTS: Good afternoon. I'm John  
21 Roberts. I'm the director of healthcare for the  
22 Uniform Code Council. We're the largest standards body

1 in the world. I'd like to thank the Food and Drug  
2 Administration for this opportunity to talk about  
3 patient safety.

4 The proposed rule to mandate barcoding at the  
5 unit dose level is essential to improving the quality  
6 of patient care. Medication errors are deadly and  
7 costly, and can have a devastating impact on the  
8 healthcare industry.

9 Rather than ask the FDA to select a single  
10 symbology, such as reduced-space symbology or composite  
11 symbology, I instead ask you to endorse the EAN/UCC  
12 system for the barcoding of all healthcare products in  
13 the United States, and let the marketplace decide what  
14 symbol goes on what package, and uses our data  
15 structure. Our data structure already encodes NDC, lot  
16 number, expiration date, serial number, and a hundred  
17 other different data structures.

18 Barcoding of all healthcare products down to  
19 the unit dose has been a goal of the EAN/UCC system.  
20 The Uniform Code Council and EAN International  
21 developed the reduced space symbology and composite  
22 symbology specifically to address this need.

1           Manufacturers, healthcare providers, and  
2 leading industry groups have been working with us for  
3 the past five years to develop a solution that brings  
4 greater automation accuracy and information detail to  
5 small healthcare products.

6           What is important to note is the reduced space  
7 symbology and composite symbology are just the latest  
8 tools of this system. The EAN system is used by nearly  
9 a million companies conducting business in 140  
10 countries around the world. These standards for  
11 product identification and electronic communication  
12 allow companies to bring greater accuracy and  
13 efficiency to products and the corresponding flow of  
14 information.

15           The EAN/UCC system is used by 23 major  
16 industries worldwide and provides a global language for  
17 companies to identify products, assets, shipping  
18 containers, and locations throughout the supply chain.  
19 This system has a strong presence in the healthcare  
20 industry.

21           Nearly 10 percent of the Uniform Code  
22 Council's membership comes from healthcare. That's

1 18,000 of our 260,000 members in North America alone,  
2 including manufacturers, retailers, distributors, and  
3 healthcare providers.

4           The overwhelming majority of all products  
5 purchased by hospitals utilize the EAN/UCC system,  
6 whether it is linens, cleaning supplies,  
7 medical/surgical products, food, pharmaceutical  
8 products, beds, or even flowers, everything a hospital  
9 purchases is encoded with our system of barcodes and  
10 standard structures.

11           Wherever the healthcare industry has a  
12 presence in the hospital and drugstores or grocery  
13 stores or any retail store selling over-the-counter  
14 products, the EAN system is at work. For nearly  
15 30 years, the Uniform Council has provided barcode  
16 innovations and has benefitted consumers and industry  
17 alike.

18           By selecting RSS and CS, the healthcare  
19 industry will be able to utilize their existing  
20 investment in the EAN/UCC system because it uses the  
21 same data structure as the other symbols. This will  
22 cause the least disruption to the healthcare supply

1 chain. It will also allow the industry to implement  
2 the FDA mandate faster. Radical system upgrades will  
3 not be an issue, so the industry can quickly respond  
4 and address the need to reduce medical errors.

5 As a part of the EAN/UCC system, RSS and  
6 composite symbology are globally recognized standards.  
7 There was a question before about question before about  
8 what the Europeans are doing for medication errors.  
9 They are very concerned about them because I have  
10 e-mails with them back and forth. The Japanese right  
11 now, their parliament is looking into this right now  
12 and they're in session right now.

13 For medical/surgical items, there is a  
14 standard out there. In 1999, the Japanese healthcare  
15 industry mandated barcoding on medical/surgical  
16 products, to include G-10, lot number, expiration date,  
17 and quantity. It took place in 2001. So the Japanese  
18 have done this already.

19 Universal guidelines of our system have been  
20 established for the placement of symbols, density, and  
21 texture, and ANSI grade of the symbol for commercial  
22 use. These guidelines could be modified by industry

1 consensus, and have been.

2           RSS and composite can be printed, scanned, and  
3 verified by readily available commercial equipment.  
4 Two of the leading scanner manufacturers, Symbol and  
5 HHP, tell us that there are an estimated two million  
6 scanners in the commercial marketplace today that can  
7 read RSS or composite.

8           The UCC knows of at least two major  
9 pharmaceutical firms that are now labeling or about to  
10 label their products with RSS and composite symbology  
11 for commercial distribution.

12           It is also important to note that UCC is a  
13 neutral, not-for-profit standards organization. The  
14 Council does not sell barcodes, software, scanners, or  
15 a proprietary solution. There is no vested interest in  
16 promoting RSS and composite to the FDA today.

17           Our system is open and voluntary. The patents  
18 for RSS and composite, like all our standards, have  
19 been placed in the public domain, freely available to  
20 any company that wishes to use them. The reason the  
21 EAN/UCC system is globally successful is that any  
22 company in any industry anywhere in the world can use

1 our barcode and electronic standards and dramatically  
2 improve the accuracy, speed, and efficiency of their  
3 business.

4 Accuracy is essential to reducing medication  
5 errors, and one of the important benefits of RSS and  
6 composite is that the healthcare industry will be able  
7 to utilize their existing supply chain infrastructures  
8 for the use of the system.

9 In closing, we believe the FDA should pick a  
10 system that improves patient safety, not just a  
11 particular barcode. I am confident the UCC and the  
12 EAN/UCC system can provide tools and global strength to  
13 help the FDA improve the quality and safety of patient  
14 care in the United States. Thank you.

15 MS. DOTZEL: Thank you. Again, I'm going to  
16 just urge the speakers to please pay attention to the  
17 timer over here.

18 MR. TERWILLIGER: My name is John Terwilliger,  
19 also with the Uniform Code Council. I am responsible  
20 for directing our various activities across those 23  
21 sectors.

22 I would like to thank the Food and Drug

1 Administration for the opportunity to speak this  
2 afternoon about patient safety and medication errors.  
3 This is an issue that the Uniform Code Council takes  
4 very seriously, and we have been working with members  
5 of the healthcare industry -- pharmaceutical  
6 manufacturers, drugstore retailers, medical/surgical  
7 product companies, and healthcare providers -- to  
8 important a solution to address this problem. The  
9 Uniform Code Council has been at this for about eight  
10 years in this whole area of improving patient safety.

11 As John just mentioned, patient safety cannot  
12 be fully solved by simply selecting a barcode. The  
13 Uniform Code Council strongly believes that the best  
14 way to solve the problem of medication errors is to  
15 select not a symbology but a system. And the system  
16 that provides best performance, global acceptance, and  
17 greatest visibility is the EAN/UCC system.

18 This system provides the strength the FDA  
19 needs to enable quick response to reducing patient  
20 medication errors. For almost 30 years, our barcodes  
21 and electronic commerce standards have been used in  
22 healthcare for both retail and non-retail applications.

1 Our system of standards is widely established in  
2 healthcare and adjacent industries, which will allow  
3 your mandate to be quickly and effectively implemented.

4           The system is global and will allow  
5 pharmaceutical companies to use a single barcode system  
6 to uniquely identify their products anywhere in the  
7 world, whether they be retail or non-retail. And a  
8 strong consumer focus has always been at the heart of  
9 our system. It's always about the end user, when you  
10 get down to it.

11           A PriceWaterhouse Coopers study that we had  
12 done stated that the UPC alone in the U.S. grocery  
13 industry has saved American consumers approximately  
14 \$17 billion annually, which has enabled greater  
15 accuracy, lower food prices, and consumer convenience.  
16 This is something that has all happened, and we don't  
17 even think much about it. But there's been a lot of  
18 money saved.

19           It is because of this track record of  
20 performance that the FDA can select the EAN/UCC system  
21 with confidence. Reduced space symbology and composite  
22 symbology have been specifically developed by the

1 Uniform Code Council and the members of the healthcare  
2 industry to improve patient safety by improving  
3 identification accuracy at the unit dose level and all  
4 other levels of packaging.

5 The EAN/UCC system has had the NDC embedded  
6 into it, into the global trade item number, for more  
7 than 25 years. The very genesis of this system was to  
8 make sure that the NDC number could be incorporated  
9 directly.

10 I'd like to make a few points regarding the  
11 FDA's proposed rulemaking and how the EAN/UCC system  
12 meets the proposed requirements and provides the  
13 greatest performance.

14 First, this system is the de facto standard in  
15 the over-the-counter retail market, both domestically  
16 and in 140 countries around the world. While NDC  
17 identification is important, this requirement would be  
18 unnecessary in the over-the-counter segment because  
19 healthcare manufacturers and drug retailers are already  
20 using barcode standards, the global trade item number,  
21 or UPC, more simply, to accurately, uniquely, and  
22 globally identify OTC products. Mandating the NDC for

1 OTC products would add costs to healthcare and provide  
2 no benefit. These products are already uniquely  
3 identified per standard. There is no reason to pick  
4 another one.

5           Second, the EAN/UCC system's strength and  
6 flexibility eliminates the need for a new NDC at every  
7 level of packaging. This has been a concern some have  
8 mentioned. It's important to know that per the  
9 standard, a manufacturer can change the indicator digit  
10 which will reflect the particular packaging level,  
11 whether it's the unit dose, an intermediate carton, a  
12 case, or maybe a whole pallet of product, without  
13 changing the NDC number. This will eliminate costly  
14 and unnecessary processes that add no value to the  
15 quality of patient care.

16           And the third point is that the EAN/UCC system  
17 already accommodates secondary information such as lot  
18 number and expiration date uniquely. That's very  
19 important. We have a way to uniquely identify those.  
20 Plus we can include other information such as serial  
21 number, if you begin to think about things like devices  
22 where the serial number is actually used. We have a

1 way to uniquely identify serial numbers also.

2           Reduced space symbology and composite  
3 symbology can incorporate this secondary information to  
4 facilitate accurate recalls, enhance inventory  
5 controls, and improve drug traceability. It is  
6 important to add that secondary information can be  
7 carried in the composite symbol over the barcode  
8 symbologies of the EAN/UCC system.

9           The UCC is working not only with the  
10 healthcare industry, but leaders of many industries, to  
11 use this system to improve identification and  
12 traceability throughout the global supply chain. In  
13 this post-September 11th world, these enhancements will  
14 provide immeasurable contributions to public confidence  
15 and the safety of our medicines, food, and everyday  
16 essentials.

17           With the EAN/UCC system, improved medication  
18 accuracy can be achieved. Most importantly, the  
19 healthcare industry would be better positioned to  
20 deliver an even higher quality of patient care. Thank  
21 you.

22           MR. PATTERSON: I am Bert Patterson. I'm a

1 pharmacist, and I'm also the vice president of  
2 contracting for Premier.

3           On behalf of the more than 1600 leading not-  
4 for-profit hospitals and health systems allied with  
5 Premier, I thank the Food and Drug Administration for  
6 holding this important meeting on health industry  
7 adoption of barcode.

8           For health providers, purchasers, and  
9 suppliers nationwide, tapping the potential of new and  
10 emergent technology is an integral component of  
11 strategic thinking, planning, and execution. Health  
12 industry observers herald the potential of technology  
13 to promote quality of care improvement and great cost  
14 efficiency through a merger of private sector  
15 initiatives and public policy.

16           Premier strongly supports the adoption via FDA  
17 regulation of an electronically readable uniform health  
18 industry data standard incorporating the universal  
19 product number, UPN, displayed at every level of drug,  
20 device, and biological packaging for the transmission  
21 via barcode technology into hospital and vendor  
22 information systems. We applaud the FDA's efforts to

1 solicit industry insight and input into the components  
2 necessary for successful regulation.

3 UPN implementation and the use of  
4 electronically readable identification has vast  
5 potential for improving healthcare safety and quality,  
6 facilitating clinical product and service, innovation,  
7 and enhancing cost efficiency at the supply chain  
8 level.

9 The requisite barcode technology exists today.  
10 It is widely used, and with documented success in  
11 countless other industries, the retail sector perhaps  
12 being the most familiar. Premier as a company will  
13 require the inclusion of barcodes on all prescription  
14 products that are put under contract at Premier as of  
15 July 1, '03.

16 Implementation within healthcare has been far  
17 less extensive of this technology, particularly at the  
18 unit of use level. I must underscore that the failure  
19 of our health systems to enhance the technology and the  
20 UPN does not imply reticence on the part of our  
21 hospitals. Hospitals, in fact, are eager to develop  
22 and deploy this kind of technology to improve the

1 quality of care they provide and to achieve economic  
2 efficiencies throughout the supply chain.

3 In this regard, I wish to focus on three  
4 important areas in which the UPN and electronically  
5 readable identification as an essential e-health  
6 initiative can achieve sustainable improvements in  
7 patient health and safety.

8 The UPN and barcoding have vast potential to  
9 facilitate sustained quality improvement and medical  
10 error reduction, generate industry-wide cost savings  
11 and efficiencies, and enhance knowledge transfer and  
12 engender quality improvement through the use of  
13 comparative data.

14 While the causes of medical errors and other  
15 adverse events are complex, system-based, and deeply  
16 rooted, the most immediate and far-reaching remedies  
17 lie in the implementation of technology.

18 As numerous interdisciplinary studies have  
19 documented, patient safety will be improved, sustained,  
20 and reinforced beginning at the supply chain through  
21 industry adoption of a standardized system of machine-  
22 readable coding on all medication packages and medical

1 devices.

2 Technology advances over the last few decades  
3 permit data of ever-increasing complexity to be  
4 embedded within barcodes, making possible the coding of  
5 increasingly smaller and varied drug and device  
6 packaging. The technology is out there. It can be  
7 done.

8 In addition to this potential for improving  
9 patient safety, UPN implementation can generate  
10 significant cost savings and efficiencies across the  
11 supply chain. Unlike pharmaceuticals, to which unique  
12 National Drug Code numbers are assigned, medical and  
13 surgical supplies and devices have no such standardized  
14 identification. Clearly, this renders web-enabled  
15 linkage of information systems, even for the purposes  
16 of comparison, anything but seamless.

17 Federal regulation and support of a  
18 standardized system for identification for medical and  
19 surgical supplies would greatly facilitate industry  
20 compliance and broad-based implementation of these  
21 technologies.

22 The 1996 EHCR report predicted that UPN

1 implementation would yield an annual savings of  
2 11.6 billion in healthcare supply chain costs. These  
3 projected savings are based on the automation of  
4 transactions and the integration of a frictionless data  
5 stream from point of manufacturer to point of use.  
6 EHCR projects that upon standardization adoption of the  
7 UPN across the healthcare supply chain, investments in  
8 automated transactions would likely bring the highest  
9 returns.

10 Finally, UPN implementation holds great  
11 promise for knowledge transfer and quality improvement  
12 through the analysis and subsequent application of  
13 comparative data. Prospective Premier signature  
14 healthcare informatics product is the most complete  
15 cost-based test-level clinical and financial data  
16 warehouse in the country, permitting peer group  
17 comparison at the level of resource consumption. In a  
18 nutshell, this would enable us to provide an apples-to-  
19 apples comparison of hospitals' clinical experience on  
20 multiple levels.

21 In conclusion, Premier believes that adoption  
22 of an industry standard and requirement of machine-

1 readable identification is a critical e-health  
2 initiative with the potential to yield significant  
3 progress in patient safety, quality improvement, and  
4 cost efficiency.

5           On behalf of Premier, its hospitals and  
6 alternate care facilities' patients, I appreciate  
7 having this opportunity to attest the potential of  
8 technology to reduce the occurrence of medical  
9 misadventures, including medication errors, and to  
10 positively impact development of e-health and the  
11 future of the industry. Thank you.

12           MS. DOTZEL: Thank you.

13           MR. O'BRIEN: Good afternoon, ladies and  
14 gentlemen. I'm Terry O'Brien, president and founder of  
15 Meds Alert USA, Incorporated.

16           Why not read barcodes in the home? Isn't that  
17 where most of the medication errors occur? Would it  
18 surprise you to know that barcodes can be read in the  
19 home today?

20           As we all know, barcodes are being targeted  
21 as a way to reduce medication errors and increase  
22 productivity of the healthcare delivery system. We've

1 begun work with the University of Tennessee to that  
2 end. We are seeking a strategic partner, and what a  
3 better one than the FDA.

4 Meds Alert systems will save lives and save  
5 money, 6- to \$800 million a year in Medicaid housing  
6 costs only if the Meds Alert barcoded system were used  
7 in Illinois. This is according to Governor Ryan of  
8 Illinois, and the Director of Aging, Margo Schreiber.  
9 It would keep people out of nursing homes for mixing up  
10 their medications. A recent study has said that we are  
11 spending \$177 billion a year to correct medication  
12 errors.

13 Meds Alert has developed and patented a system  
14 to bring the use of barcoded medicine, caregivers,  
15 supplies, and equipment into the patient's home or the  
16 patient's institutional setting. Meds Alert was  
17 granted patents by the U.S. Patent Office within six  
18 months because, under patent law, if it would help a  
19 cancer or an AIDS patient, they would put it at the top  
20 of the list. We received both patents.

21 We also have international patent rights for  
22 most of the industrialized world. Meds Alert

1 communications links are wire telephone, cable TV,  
2 wireless, and cell phones. Meds Alert raises  
3 prosecution compliance by signaling the patient in any  
4 language to take their medication.

5 We verify by having them read the -- pass the  
6 prescription vial in front of a barcode reader that  
7 they have the correct medication. If they don't, we  
8 tell them not to take it. If they insist on that, we  
9 sound an alarm for noncompliance and send over a  
10 caregiver or call 911. We also provide a safe home  
11 environment for these people.

12 Good care is compromised by patient  
13 noncompliance. Illiterate or those with low health  
14 literacy have trouble reading prescription labels and  
15 medical forms. Barcodes offer a solution.  
16 Noncompliance often leads to emergency room visits or  
17 institutionalization. The average cost for a nursing  
18 home today is approximately \$50,000 a year.

19 Additionally, the Kaiser Foundation on May 2nd  
20 just released a study where 4,000 women were studied  
21 and found that 21 percent did not even fill their  
22 prescription. Meds Alert has a system for that, too.

1 We call it rescribe.

2           According to Kiplinger, the newsletter of  
3 6/14, people with chronic diseases are only 20 percent  
4 of those insured but make up 80 percent of the  
5 healthcare cost. Chronic disease management is the one  
6 area sure to reduce healthcare cost.

7           In a Time Magazine article, Dr. Victor  
8 Villagra, president of the Disease Management  
9 Association and an executive of CIGNA, has 600,000  
10 members enrolled in a chronic care program for  
11 diabetics. He has seen a cost savings of 14 percent.

12           But he said, and I quote, "This is no longer  
13 sufficient. What is, apparently, is having someone  
14 tell you to take your medication or else." And I'm  
15 wondering if Medicare or Medicaid may be headed in this  
16 direction.

17           Meds Alert reminds someone to take their  
18 medication and records the event. Who are the  
19 chronically ill? There are patients who suffer from  
20 heart disease, diabetes, asthma, AIDS, cancer, and as  
21 yet uncounted, I believe, the two million plus organ  
22 transplant recipients. And I'm wondering if cognitive

1 impairment is counted as that as well.

2           The coming tidal wave of baby boomers will  
3 make up 26 percent of the population by 2010, and along  
4 with them come the chronic diseases and cognitive  
5 impairment. Another serious condition that they bring  
6 with them is depression.

7           There are shortages in all areas of  
8 healthcare. Caregivers: Daughters primarily provided  
9 most home health care, but now most work. Nurses:  
10 It's estimated that over 60 percent of them are 40  
11 years old, and we need replacements. According to Dean  
12 Gorley at the University of Tennessee, there are 10,000  
13 pharmacy jobs with no one to fill them.

14           Low wages are another problem. The average  
15 paid caregiver, according to a Chicago Tribune article,  
16 says that the average caregiver in Illinois makes  
17 \$18,000 a year. That's not enough to pay for an  
18 apartment or for food.

19           The only way to handle the overwhelming  
20 problem is automation, barcoded unit dose packaging.  
21 Senator Kennedy is on record, and others, that they  
22 will introduce litigation this year to reduce

1 healthcare costs by mandating they use automation.

2 Barcodes must be part of that technology automation.

3           The national barcode standard: How close is  
4 it? After today, I see that we're working on it and  
5 still working on it. But I know that the Uniform Code  
6 Council, Health and Human Services, the U.S.

7 Pharmacopeia, and NCCMERP, as well as U.S. drug  
8 manufacturers, should want a standard.

9           Meds Alert stands ready with its patented  
10 technology to address unit dose packaging. We have a  
11 demonstration unit completed, and we welcome discussion  
12 with other entities. Our patents allow for migration  
13 and expansion. And I thank you for your interest.

14           MS. DOTZEL: Thank you.

15           MR. SIM: Good afternoon. My name is Mike  
16 Sim. I'm the chief executive officer of ADVIAS, which  
17 is a Virginia-based company specializing in advanced  
18 information assurance solutions. We do biometrics in a  
19 barcode.

20           You will detect from my accent that I'm not  
21 from the U.S. In fact, I've lived most of my life in  
22 the U.K., having only been here since September.

1 Questions were asked this morning, what's happening in  
2 Europe in healthcare? I think I probably know the  
3 answer, having spent 25 to 30 years of my life in  
4 healthcare in the U.K.: Very little.

5 Most of the effort, particularly on barcoding,  
6 I think was undertaken by myself. I spent two years  
7 canvassing to get barcoding used in drug prescriptions  
8 for general practice. At the end of that two years,  
9 the government was very encouraged, and they said, this  
10 has gone almost to the top of the list. This is the  
11 second option now. I asked, what's the first option?  
12 And they said, no change. And I think there was a very  
13 response this morning.

14 Okay. What's a Brit doing here in the U.S.?  
15 Basically, I've spent the last six years, having come  
16 into the drug industry and a nurse by profession,  
17 looking at ways to secure drug delivery. I've been  
18 saddened today hearing some of the responses here about  
19 barcoding and how far the technology actually goes  
20 because I believe it goes a lot further.

21 We have been very forward-thinking in the  
22 U.K., and in fact we have a number of systems already

1 running, and running quite well. I won't go over all  
2 the problems in the system here in the U.S., or  
3 anywhere, really, because those have been covered  
4 today, and I think we're all very aware that the wrong  
5 patients get the wrong drugs. And even with the most  
6 sophisticated pharmacy systems, the wrong drug can get  
7 taken off the shelf, and once the label is applied, we  
8 all know the consequences.

9 But I think it's also very important to look  
10 at -- there have been a number of points today about,  
11 you know, do we need to really put additional barcoding  
12 on the cover for manufacturer expiry dates. Well, I  
13 think we do because the problem is -- the question was  
14 asked, how many incidents are there of adverse effects  
15 to drugs that have run out of date or drugs which have  
16 manufacturing problems? We don't know the answers  
17 because we have no way of tracking the drugs.

18 The system today is, if a drug manufacturer  
19 finds a problem in their stock, they'll send out a  
20 letter to their wholesalers, and the wholesaler will  
21 write to the hospitals, and they'll write to doctors,  
22 and they'll write to nursing homes, and there's a

1 cascade of letters that go out. But there is no way of  
2 tracking those drugs.

3 Nor is there any way of correlating the  
4 effects that have occurred with those drugs. And in  
5 fact, it will probably need some real clinical evidence  
6 to actually show that there is an effect when these  
7 drugs are out there.

8 And the U.K. is exactly the same for that.  
9 They haven't done anything better, and I don't think  
10 the whole of Europe. I hear that the Japanese are  
11 moving forward, and I'm not at all surprised.

12 Given that we've got this problem with  
13 identifying patients and supplying medication, we also  
14 have to look at what's the common link in the supply  
15 chain? Well, the common link is the barcode. It is  
16 coming through. Manufacturers increasingly now are  
17 marking their drugs with barcodes; sadly, not all of  
18 them. I think in the U.K. we've got a much higher  
19 proportion than you've got.

20 But even if the original pack comes in in a  
21 barcode format, perhaps to the barcode format with  
22 manufacturer date, expiry date, et cetera, it's then

1 possible, if they have to repackage, to actually copy  
2 that through the process.

3 My company has been looking primarily at all  
4 the barcodes that are available today, and there are  
5 quite a range of barcodes. Now, this morning I heard  
6 talk of should we in fact be having a single barcode  
7 that refers -- that's a reference?

8 Well, unfortunately, not all care is in  
9 hospital. A lot of care may be in hospital. A lot of  
10 care may be in outpatients. But a lot of care may be  
11 at the roadside. I mean, it may be the paramedics  
12 delivering drugs. It may be doctors going out and  
13 visiting people in hospitals.

14 And we need to be able to access that  
15 information from those drugs wherever we treat them.  
16 And I believe the only way to do that is to put a  
17 2D barcode on those drugs so that you can actually use  
18 equipment. We don't have the luxury of radio  
19 connectivity when we're in a patient's home or when  
20 we're lying on the roadside.

21 The 2D barcodes that we've primarily worked  
22 with is PDF-417, which was developed by Symbol

1 Technologies. The vast majority of you, if you take  
2 your driving license out, you'll find it on the back of  
3 your license, or military, on the back of your ID.  
4 It's a tried and tested product that reads -- sorry.

5 MS. DOTZEL: Thank you.

6 MR. WENIGER: My name is Bruce G. Weniger.  
7 I'm the assistant chief for vaccine development at the  
8 Vaccine Safety and Development Branch of the National  
9 Immunization Program at the Centers for Disease Control  
10 and Prevention in Atlanta. I thank the Food and Drug  
11 Administration for this opportunity to comment on the  
12 issue of mandating identifying barcodes on primary  
13 pharmaceutical packaging.

14 For the past several years, I have coordinated  
15 the Vaccine Identification Standards Initiative, known  
16 as VISI, or V-I-S-I, which is a collaborative effort by  
17 a variety of public health agencies and private  
18 organizations and groups involved in the practice of  
19 immunization, including medical and nursing  
20 associations and the vaccine industry itself. Full  
21 information about VISI and its recommendations are  
22 available at our website, [www.cdc.gov/nip/visi](http://www.cdc.gov/nip/visi).

1           The purpose of VISI is to establish voluntary  
2 uniform guidelines for packaging and labeling of  
3 vaccines and the recording of their identifying  
4 information. The goal is to improve the accuracy and  
5 convenience of transferring vaccine identifying  
6 information into medical records and immunization  
7 registries, and thus to enhance the monitoring of  
8 immunization programs and their surveillance for  
9 adverse events following vaccination.

10           The National Childhood Vaccine Injury Act of  
11 1986 mandates that all persons who administer  
12 recommended childhood vaccines must record the vaccine  
13 identity and lot number in the medical record.  
14 However, evidence from the Vaccine Adverse Events  
15 Reporting System, or VAERS, which CDC runs jointly with  
16 the FDA, suggests that from 10 to 20 percent of medical  
17 records lack these lot numbers.

18           CDC's separate vaccine safety datalink project  
19 monitors the vaccination and medical experience of a  
20 cohort of 2-1/2 percent of the U.S. population through  
21 a network of HMOs. It finds a similarly high frequency  
22 of nonexistent lot numbers recorded, and ambiguous

1 vaccine identities, probably as a result of  
2 transcription errors and handwriting ambiguity.

3           Among the six major recommendations of VISI,  
4 the first is for vaccine vials and prefilled syringes  
5 to have RSS, reduce size symbology, barcoding and  
6 duplicate or triplicate peel-off stickers containing  
7 the National Drug Code, expiration date, and lot  
8 number. This information could then be readily  
9 captured into the medical records and other forms,  
10 either electronically or by old-fashioned peel-off and  
11 pasting.

12           We have learned in VISI from our consultations  
13 with printing experts in online printing and barcoding  
14 experts that the label printing technology has made  
15 many advances in recent years that make this  
16 recommendation feasible today.

17           This new technology includes labels with  
18 multiple layers and peel-off stickers as well as high-  
19 resolution, high-speed printers that can print barcodes  
20 at the time of vial filling, or online printing in  
21 industry parlance. This is important because lot  
22 numbers and expiration date are usually assigned on the

1 day of filling and cannot be preprinted on the label  
2 stock.

3 In my written statement, which will be in the  
4 docket, I understand, are photos illustrating examples  
5 of these multiple peel-off stickers and the reduced  
6 size barcoding on vaccine vials. I have samples with  
7 today. I'm happy to pass them around to the panel and  
8 to the audience. Hopefully I'll get them back at the  
9 end of the day.

10 The remaining five components which VISI  
11 recommends include -- and by the way, if you don't want  
12 to wait for the docket, if you'll send me an e-mail at  
13 bgw2@cdc.gov, I'll be happy to send you the statement  
14 with the photographs.

15 The remaining five components which VISI  
16 recommends include full barcoding on the outer  
17 cardboard or secondary vaccine packaging of the  
18 National Drug Code, the expiration date, and the lot  
19 number. Currently, only the NDC is routinely barcoding  
20 now, and that's because the National Wholesale  
21 Druggists Association insisted on it years ago.

22 Third, a uniform vaccine administration record

1 form to receive the peel-off stickers for non-  
2 computerized medical practices.

3 Fourth, a user-friendly National Drug Code  
4 vaccine database on the web to assist software  
5 developers and others to identify vaccines from their  
6 NDC and vice versa, and in the future to convert them  
7 to other coding systems like CPT and HL-7.

8 Fifth, a vaccine facts information sidebar on  
9 outer cardboard packaging in order to standardize the  
10 format and location of key information for safe  
11 administration of vaccines, as the FDA has done so  
12 wonderfully with its mandated and highly appreciated  
13 nutrition facts sidebars on food.

14 And sixth, standardized abbreviations for  
15 vaccine types and vaccine manufacturers to save real  
16 estate on small peel-off stickers on these vaccine  
17 vials.

18 We would particularly urge FDA, in mandating  
19 barcodes on unit of use packaging, to specify the use  
20 of numbering systems and reduced-size two-dimensional  
21 barcoding symbologies promulgated by the EAN/UCC, an  
22 international collaboration of nonprofit standards

1 organizations which already set the guidelines for the  
2 existing barcodes we now see on pharmaceuticals, foods,  
3 and most other products of global commerce. This would  
4 avoid the headaches and confusion of a Balkanized  
5 system in which manufacturers might use diverse or ad  
6 hoc numbering systems or barcode technologies.

7 This could result in much extra work and  
8 expense if hospitals and clinics were thus required to  
9 set up customized systems to read them all rather than  
10 use off-the-shelf hardware and software. Better to use  
11 an existing global ID numbering standard already at  
12 work in many U.S. hospital receiving docks, warehouses,  
13 and pharmacies.

14 Finally, we would suggest that both expiration  
15 date and lot number are important data fields for both  
16 future bedside monitoring and accurate assurance  
17 systems, as well as for existing national drug and  
18 vaccine safety surveillance systems. Thank you.

19 MR. KRAWISZ: My name is Bob Krawisz. I'm  
20 executive director of the National Patient Safety  
21 Foundation. Prior to joining the National Patient  
22 Safety Foundation, I was director of business

1 development for the American Society for Quality and  
2 vice president of the National Safety Council.

3 I'm here today to speak in favor of barcoding  
4 regulation. The Institute of Medicine reports that  
5 more than 7,000 inpatient deaths per year nationwide  
6 are attributable to medication error. Research shows  
7 that medication errors occur when flaws in the  
8 medication administration process lead to human error.

9 As we have heard today, a promising strategy  
10 to help avoid these errors is using barcoding to  
11 automate aspects of the process. And I think the time  
12 is now to take that action.

13 Barcoding has been used effectively for  
14 decades by supermarkets and other businesses, including  
15 healthcare, to reduce errors, improve quality, and  
16 lower costs. Documented improvements in accuracy have  
17 approached the level of six sigma, and improvements in  
18 productivity range from 30 to 50 percent.

19 If anyone really cares to look at a variety of  
20 case studies, the Association for Automatic  
21 Identification and Data Capture Technologies on their  
22 website have more than a hundred case histories of

1 using barcodes, and the improvement in accuracy that  
2 was obtained, and also the improvement in productivity.

3

4           Barcoding can easily be adapted to medication  
5 administration. By printing scanning codes on  
6 medication labels and on patient ID bands, machines can  
7 readily discriminate one item number from another and  
8 identify mismatches.

9           Integrating this technology with a prescriber  
10 order entry system and unit dose barcode medication  
11 labeling creates an efficient and accurate electronic  
12 medication administration system.

13           Kay Willis this morning pointed out that the  
14 VHA has taken a leadership role in developing systems  
15 with outstanding results in error reduction.  
16 I think she pointed out actual improvements of around  
17 84 or 85 percent in error reduction.

18           Given a compliance achieved by the Department  
19 of Defense and the commitment being made by other major  
20 suppliers to support barcoding, now is the time for  
21 healthcare organizations to make barcoding part of  
22 their overall quality and safety strategy.

1           Kasey Thompson indicated that the American  
2 Society of Health System Pharmacists supports marking  
3 each container with a standard, compact,  
4 multi-dimensional barcode that would contain a reliable  
5 drug identifier, lot number, and expiration date that  
6 any software program could scan, decode, and report.

7           A single scan could be used to inform users  
8 whether they have the right drug and whether the drug  
9 had expired. That scan would support lot number and  
10 expiration date tracking, which is impractical in many  
11 of today's systems because of overhead costs and data  
12 capture.

13           The barcode printing and scanning technologies  
14 necessary to support this ideal exist today. Lacking  
15 such an ideal system, the use of a HBT-compliant  
16 barcode containing the NDC code on every container  
17 would provide a significant advance.

18           It is recognized that labeling changes create  
19 significant regulatory burdens for drug manufacturers,  
20 and smaller containers pose label formatting problems  
21 that must be overcome. However, some manufacturers  
22 have already found solutions to these problems. FDA

1 and/or purchaser mandates are required to move all drug  
2 producers to the next level of patient safety. Thank  
3 you.

4 MS. COUSINS: Good afternoon. My name is Diane  
5 Cousins, and I'm here representing the United States  
6 Pharmacopeia.

7 USP sets legally enforceable standards for  
8 drug products in the United States that include  
9 packaging and labeling as well as quality, strength,  
10 and purity. We have been operating a medication error  
11 reporting program since 1991, and we spearheaded the  
12 formation of the National Coordinating Council for  
13 Medication Error Reporting and Prevention.

14 In June of 2001, the National Coordinating  
15 Council issued a set of seven recommendations which  
16 include a call to action that USP and FDA collaborate  
17 with pharmaceutical manufacturers and other appropriate  
18 stakeholders to establish and implement uniform barcode  
19 standards down to the immediate unit of use package.

20 The Council also urged the expeditious  
21 implementation of its recommendations so that  
22 healthcare practitioners and organizations could

1 benefit from machine-readable codes present in a  
2 standard format on unit of use medication packaging.  
3 USP fully supports the Council's recommendations.

4           Insofar as USP is concerned, USP could provide  
5 standards for barcoding requirements that would be  
6 enforceable under the FD&C Act for official articles.  
7 USP awaits the definition of FDA's regulatory authority  
8 in order for USP to determine how best to support and  
9 compliment these requirements.

10           Because many states recognize our labeling  
11 requirements, USP's barcoding requirements could be  
12 extended to practice situations such as computerized  
13 prescribing and pharmacy dispensing labels.

14           Label readability and product identification  
15 have been ongoing issues important in tracking and  
16 controlling product quality and information as the  
17 pharmaceutical product moves from the manufacturer to  
18 the patient.

19           Based on medication errors reported through  
20 the USP reporting programs, confusion over the  
21 similarity of drug names accounts for approximately  
22 15 percent of reports submitted, and as many as

1 33 percent of reports cite labeling and packaging  
2 concerns that contribute to medication errors.  
3 Barcoded products can help reduce such errors, and have  
4 broad impact that spans the multiple phases and  
5 settings of healthcare delivery.

6 USP views the barcode requirement as a part of  
7 a larger medication error prevention approach, which  
8 includes useful and clear names for compendial  
9 articles, imprint codes, label simplification, and even  
10 standardized prescription ordering.

11 USP is developing new general information  
12 chapters on unit of use packaging that may include a  
13 discussion of barcodes. USP is considering the  
14 advisability of developing other general information  
15 chapters that would include guidelines regarding  
16 imprint codes and label readability.

17 Therefore, USP supports the December 3 Federal  
18 Register proposal, but believes that exemptions should  
19 be issued at this time for certain containers,  
20 specifically ampules of 5 milliliter size or less,  
21 based on the limitations of current technology to  
22 accurately and consistently convey information for such

1 package sizes.

2           USP also supports the December 3 Federal  
3 Register proposal regarding human drug labeling. USP  
4 encourages FDA's expeditious implementation of such a  
5 regulation.

6           In closing, USP recommends that a barcode  
7 contain, at a minimum, the product NDC number, lot  
8 number, and expiration date. This recommendation is  
9 contingent on FDA's revision of the current NDC system  
10 to provide greater accuracy and consistency to those  
11 codes.

12           Barcodes should be standardized in format and  
13 information, and should be present on packaging at the  
14 point of care, but should not replace human-readable  
15 labeling. Thank you.

16           MR. COHEN: I'd like to thank FDA for giving  
17 me the opportunity to speak, and also to all of you,  
18 thanks for showing up today and supporting barcoding.

19           My name is Michael Cohen. I'm a pharmacist,  
20 and I'm president of the Institute for Safe Medication  
21 Practices. It's a nonprofit organization located in  
22 Huntington Valley, PA. And we work pretty closely with

1 practitioners, healthcare organizations, regulatory  
2 authorities, and standards organizations in initiatives  
3 to prevent medication errors.

4           Yesterday, for the third time in my career --  
5 I guess it's a coincidence that it happened  
6 yesterday -- I was called to an organization that had  
7 a fatal medication error with potassium chloride  
8 concentrate injected directly into a patient instead of  
9 another drug.

10           And I had to face one of the individuals who  
11 was directly involved in this case, and she was  
12 entirely devastated by this incident. Remorseful as  
13 she was, there were no words that could describe what  
14 an event this was yesterday. And obviously, the family  
15 of the patient was devastated, too.

16           And I was asked, you know, for advice on how  
17 to prevent errors like this. And there are many ways  
18 to do that, of course, notwithstanding the withdrawal  
19 of potassium chloride from nursing units. One that  
20 struck me, because I was going to be here today, was  
21 obviously barcoding of the pharmaceuticals. It was a  
22 switch, a swap. She used the wrong ampule. And it

1 could have been prevented, it along with the thousands  
2 of others that you've heard about today.

3           Rather than repeat a lot of what you've heard  
4 already, because we fully believe in the idea of  
5 barcoding unit dose packaging, I'd like to talk about  
6 another aspect of this. But I do want to clarify the  
7 unit dose package and what we mean by that.

8           I'm talking about a single unit dose, a single  
9 dose. This is in contrast to the terminology unit of  
10 use, which might be a 30-day supply package in a single  
11 package. They're quite different. And what I describe  
12 is about unit dose, but all pharmaceutical packaging,  
13 including unit of use. But we would like to see the  
14 unit dose package with a barcode on it.

15           I wish to focus my attention on the need for  
16 barcodes on the unit dose package of medication, and  
17 most importantly, the barcoded unit dose packages of  
18 medications remain readily available from the  
19 manufacturers.

20           The importance of unit dose medication  
21 dispensing in the acute care setting has been advocated  
22 since the '60s by many organizations. And although

1 this is a proven safe way to provide medications in the  
2 acute care setting, especially with the recent use of  
3 barcode scanning to match patients' specific doses with  
4 the patient and the record, we're experiencing a  
5 decrease in the availability of the unit dose package  
6 by many manufacturers.

7           And our fear is that many more manufacturers  
8 will cease to provide unit dose medications if a  
9 barcoding regulation is put in place. We certainly  
10 hope that that does not occur. We believe that a  
11 regulation is needed, and I don't know how this could  
12 even be accomplished. There might even need to be some  
13 type of an incentive. But we've got to get the  
14 manufacturers to cooperate with the unit dose package  
15 itself being barcoded.

16           There are too many hospitals in rural  
17 communities that will not be able to afford robotics to  
18 do packaging from bulk. And I don't know how else to  
19 accomplish this, without the cooperation of the  
20 pharmaceutical industry.

21           And let me tell you, the readership of our  
22 newsletter is extremely concerned about the lack of

1 availability. We did a survey this past year, and I'd  
2 just like to review that very briefly. We have about  
3 6,000 hospitals that get our newsletter. And we asked  
4 them to respond to a survey. So over 500,000 people  
5 read this.

6 Three-quarters of the respondents reported  
7 problems with the unit dose packaging of both new and  
8 well-established brand oral solid products on the  
9 market, including those that had been previously  
10 available in unit dose packages.

11 A third reported about six to ten brand  
12 products that have not been available in unit dose  
13 packaging in the past year. And another quarter  
14 reported problems with 11 to 20 brand products. Over  
15 6 percent reported problems with more than 40 different  
16 brand products. Even more experienced problems with  
17 generic oral solid products.

18 Most respondents who repackage medications now  
19 estimate a 1 to 10 percent error rate when they do it  
20 on their own. So we really need you, manufacturers, to  
21 cooperate. It is critical to make this work.

22 It was clear from our survey that despite some

1 initial worry about costs, many hospitals are ready to  
2 do their part and move barcode technology forward.  
3 About half now consider the availability of unit dose  
4 packaging when making decisions about new drugs for the  
5 formulary, and two-thirds reported they'd be more  
6 likely to select a therapeutically equivalent product  
7 if it is available in unit dose packaging.

8 More to the point, 84 percent felt that a  
9 slight increase in cost would not deter them from  
10 purchasing a specific vendor's product. Only  
11 11 percent felt a slight cost increase would be a  
12 deterrent.

13 On behalf of its members, you've heard group  
14 purchasing organizations like Premier say, let's get  
15 this rolling. I hope that it doesn't take what some of  
16 the regulations take to formulate and publish in the  
17 Federal Register. I too would like to see this, as  
18 Premier said, by July next year.

19 ISMP strongly recommends that FDA require  
20 barcodes on all medications, to include the NDC number  
21 as the standard identifier for prescription  
22 medications, the medication's lot number, and the

1 expiration date.

2           However, if necessary, we support a phased-in  
3 approach, with the barcoded NDC required as soon as  
4 possible and the lot and expiration date required  
5 within a time certain. Thank you very much.

6           MS. DOTZEL: Thank you.

7           MS. ENGLEBRIGHT: Good afternoon. My name is  
8 Jane Englebright. I'm the vice president for quality  
9 at HCA, Incorporated. And I'm speaking to you today as  
10 a nurse who has given medications using a barcoded  
11 administration system, and who has seen the difference  
12 they make in medication errors. And currently, I'm  
13 working to roll out barcoding administration to all of  
14 the HCA hospitals.

15           I'm testifying today on behalf of both HCA and  
16 the Federation of American Hospitals. HCA owns and  
17 operates about 200 hospitals and other healthcare  
18 facilities in 24 states, England, and Switzerland. And  
19 the Federation is a national trade association  
20 representing the nation's privately owned and managed  
21 community hospitals and health systems from the acute  
22 and post-acute spectrum.

1           In February of 2000, HCA made a decision to do  
2 its first corporate-wide quality initiative, and the  
3 first component of that was improving medication  
4 practices. And what we set about doing was trying to  
5 improve medication safety, reduce errors, and prevent  
6 harm and injury to our patients.

7           We've done that in a comprehensive manner,  
8 looking at both operational improvements and the  
9 development and employment of two technologies, one of  
10 those an electronic physician ordering system, and the  
11 second an electronic barcode-assisted medication  
12 administration system that's used by nurses and  
13 respiratory therapists throughout our hospitals.

14           This is the technology that would greatly  
15 benefit from federal standardization of barcoding  
16 related to medications. We have 186 hospitals that  
17 will have this technology in place by the end of 2005.  
18 We have two of them currently doing it, and we'll have  
19 two per month coming on board through the rest of this  
20 year. We feel a strong sense of urgency. We firmly  
21 believe that this technology prevents injury and  
22 prevents death.

1           What we have found, to answer a few of the  
2 questions from earlier, is that even by moving our  
3 inventory in our pharmacies to preferentially buy from  
4 manufacturers who provide barcoding at the unit of  
5 dose, we still have to repackage about half of what's  
6 in our pharmacy. We have learned, with a fairly  
7 inexpensive scanning system, how to read UPC, how to  
8 read 128, and how to read RSS symbologies.

9           But we are buying packaging equipment and  
10 repackaging our medications ourselves for about  
11 50 percent of the inventory in each one of the  
12 hospitals where we're doing that. We do that  
13 understanding that we introduce a potential for a  
14 labeling error in the process of doing that, and  
15 understanding we're incurring a cost of anywhere from  
16 12 to 15 cents per dose, sometimes more for the  
17 packaging than it actually is for the pharmaceutical  
18 that's contained in there.

19           We believe the process that we've put in place  
20 where we have a patient that has their medication  
21 profile, their orders from the doctor available  
22 electronically, where each dose of medication is then

1 identified with machine-readable code, and where the  
2 patient's armband has not only human-readable but  
3 barcoded patient identifier on it, are the elements of  
4 a safe medication administration system.

5 So the nurse goes to the bedside with a  
6 computerized profile of the medication administration,  
7 scans each dose of medication to verify that that is  
8 what the doctor has ordered for this medication, and  
9 the five rights of medication administration have been  
10 observed, and then verifies the patient identification  
11 by scanning the armband.

12 At the time they file that interaction, then,  
13 we have for the first time in our hospitals a  
14 comprehensive record of all the chemicals that are in  
15 the patient's body, regardless of where in the hospital  
16 and who in the hospital has administered that  
17 medication, that's available to the physician for  
18 clinical decision-making and, maybe even more  
19 phenomenally, we have an accurate bill.

20 (Laughter)

21 With that, we would like to encourage the FDA  
22 to require the pharmaceutical industry to have

1 standardized machine-readable barcoded information that  
2 includes the NDC, the lot number, and the expiration  
3 date. We too would welcome a phased-in approach if  
4 that is necessary. We believe that the most  
5 significant medication errors, the ones that really  
6 cause damage to patients, are wrong medication and  
7 wrong dose, both of which could be prevented with the  
8 NDC number in the barcode. Thank you.

9 MR. ROBINSON: Good afternoon. I am Dr. Skip  
10 Robinson, and I have the honor of directing the  
11 clinical program for Consorta Catholic Resource  
12 Partners. We are the leading healthcare resource  
13 management company and group purchasing organization  
14 whose shareholders are Catholic-sponsored, faith-based,  
15 and nonprofit.

16 I am pleased to have the opportunity to  
17 testify to the importance healthcare industry and the  
18 people they serve the barcoding of drugs and  
19 biologicals. Consorta promotes the use of barcoding  
20 technology to create a safer, more efficient, and more  
21 effective patient care system.

22 I am here today representing the consensus

1 recommendation of our over 500 acute care hospitals  
2 representing 70,000 beds, and more than 1800 non-acute  
3 care sites.

4           As we are all aware, the relationship between  
5 technology advancement in human health, patient care,  
6 and patient safety has greatly improved the health and  
7 mortality of most Americans. However, in some  
8 respects, the healthcare industry trails far behind  
9 many industries in reaping the benefits of new  
10 technologies.

11           We practitioners are aware that we must find  
12 better ways to verify and review medications before  
13 they are administered to patients. Barcoding of unit  
14 of use medication serves to close the gap in  
15 distribution. Without it, front-end technologies such  
16 as robotic cart fills and drug interaction checks will  
17 never reach full potential. The lack of use of barcode  
18 technology without all those changes will greatly  
19 hinder patient care.

20           Consorta recognizes that the implementation of  
21 barcodes on the unit of use medication packaging is  
22 only the first vital step in recognizing the promise of

1 barcode technology and making our healthcare system  
2 safer.

3           Consorta supports the implementation of  
4 requirements of barcoding on all commercially available  
5 prescription and nonprescription medications, that  
6 barcodes should be included on the labels of all unit  
7 of use pharmaceutical products.

8           The NDC code, which is established by the FDA,  
9 should be the initial data element included on the  
10 barcodes. This should be implemented as quickly as  
11 possible. Inclusion of the expiration date and lot  
12 number, especially to track recalls and out-of-date  
13 products, should be added to the barcode as soon as  
14 technically feasible.

15           Consorta supports the eventual inclusion of  
16 medical devices for the label recommendation.

17           To conclude, Consorta recognizes that there  
18 are some costs associated with this. And we have  
19 looked and talked to our hospitals, and they are all  
20 willing and ready to aid more money to do this.

21           However, much larger expenditures will be  
22 taken out of the system because our institutions will

1 have to adopt these new technologies as they go forward  
2 because what we have to do is be able to, at the  
3 bedside, check drug/drug, drug/food interactions,  
4 laboratory values, allergies, and decisions. They must  
5 be done at bedside. Thank you.

6 MR. NEUENSCHWANDER: My name is Mark  
7 Neuenschwander. I have been a patient and I am a  
8 consultant in the field of pharmacy automation.

9 It was 27 years ago that Wrigley's opened the  
10 door by putting a barcode on a pack of chewing gum. It  
11 was really a statement of faith because grocery stores  
12 and drugstores didn't have scanners. But their faith  
13 was not in vain. Within a decade, virtually every item  
14 on the shelves of those drugstores and supermarkets had  
15 a barcode, and the vast majority of checkout stands  
16 were equipped with scanners to read them.

17 Within five years, 1990, virtually every  
18 retail item had a barcode, not just Q-Tips at Walgreens  
19 and Cheerios at Safeway, but also duct tape at Home  
20 Depot and dresses at Nordstrom's. Barcodes on  
21 everything, scanners everywhere -- almost.

22 In 1991, the first unit dose medication was

1 barcoded by a manufacturer. The door was opened. And  
2 ten years later, still two thirds of the medications  
3 that make their way from the manufacturer to the  
4 hospital bed are without barcodes, and about  
5 3 percent -- it's not 1 -- about 3 percent of our  
6 hospitals have scanners at the point of medication  
7 administration.

8           The reason? For years, drug manufacturers  
9 have argued, why should we apply barcodes if hospitals  
10 don't have scanners? And hospitals have argued back,  
11 why should we buy scanners when drugs don't have  
12 barcodes?

13           And the whole thing reminds me of a slapstick  
14 comedy. A couple of Keystone Cop cars come to a narrow  
15 bridge, not being able to cross, because the drivers  
16 are shouting back and forth, "After you." "No, after  
17 you." And it's been this way for the last ten years.

18           And I am asking you as a concerned citizen and  
19 someone who traffics in this world of healthcare, FDA,  
20 please help us get this thing across the bridge.  
21 There's a wonderful world of safety on the other side.

22           Now, what we all want is labels with

1 medications that contain machine-readable codes -- I'll  
2 use the term barcodes -- that can be read at the point  
3 of administration. And we've heard all the values  
4 about point of administration scanning.

5 I want to reemphasize one other value, and  
6 that is documentation at the point of administration,  
7 as critical to safety, in my opinion, as verification  
8 for when a doctor comes in to evaluate a patient, he or  
9 she obvious the patient, looks at the patient  
10 administration record, and right now our patient  
11 administration records are MARs.

12 Too often we treat them as if M stands for  
13 memory. A nurse comes to the end of a shift, all too  
14 often, and treats the MAR the way I'm going to treat my  
15 expense account when I get at the end of this trip,  
16 trying to remember what taxi did I take, was that this  
17 day, was the hotel this date. And we end up with an  
18 approximate MAR. I want my doctor to have an accurate  
19 MAR. Scanning at bedside helps us.

20 Now, which symbologies do we want on these  
21 labels? I'll just put it this way: today's  
22 symbologies that today's barcode readers can read. And

1 if the Dick Tracy micro-mini radio chips come in our  
2 lifetime, we can put them on top. But I'm tired of  
3 waiting. I think we all ought to be tired of waiting.  
4 Jeez, we've been waiting for Dick Tracy watches since  
5 1931.

6 Now, what exactly is it that we want barcoded?  
7 Units of use? Unit dose? And all this nomenclature  
8 has confused us for years. And as an outsider, I sit  
9 and go, what is this? What's that? And I asked some  
10 medication safety expert, "What's the difference?" And  
11 he says, "Well, my colleague and I disagree, but here's  
12 how we define it."

13 An old preacher told a young understudy, he  
14 says, "If there's a mist in the pulpit, there's a fog  
15 in the pew." Doggone it, there is a fog in the pew  
16 when it comes to barcode scanning. There is not a mist  
17 in the pulpit, though, if you go back and read the FDA  
18 definitions. We're talking about immediate containers.  
19 That's the terminology when you talk about labeling.

20 So we're asking you to barcode all immediate  
21 containers. What should it include? Obviously, lot  
22 number, drug -- I mean, excuse me, drug, strength,

1 manufacturer, lot number, and expiration date.

2 Let me just say this in conclusion, that  
3 hospitals have already started across this road. They  
4 are going pell-mell into bedside scanning. And they  
5 are -- I have been in hospitals where volunteers are  
6 slapping barcodes on syringes.

7 There are a reason why we have GMPs. And when  
8 we go ahead into barcode scanning, let's not leave  
9 those GMPs behind by having hospitals who don't have to  
10 comply with those GMPs become packaging houses just so  
11 they can scan. Let's help the manufacturers catch up  
12 to all these hospitals that are going across the bridge  
13 into the future. There's room for two on the bridge.

14 Other than that, I have no opinion.

15 (Laughter)

16 MR. WRAY: Good afternoon. I'm Bruce Wray,  
17 the director of marketing at Computype. We're a  
18 supplier of barcode labels, label printing systems,  
19 scanners, and software. We've served the blood and  
20 plasma and general laboratory markets since the mid-  
21 1970s.

22 It was my privilege back in October of 1989,

1 at a meeting in the Netherlands, to recommend to the  
2 international blood bank community that they switch the  
3 standard blood bank symbology from Codabar to Code 128.  
4 They adopted that suggestion, and the result was  
5 ISBT-128, a formal specification for the identification  
6 of human blood and blood products now being adopted  
7 throughout Europe but largely being ignored here in the  
8 U.S.

9           What did we learn as we developed this new  
10 specification? I think we learned several things.  
11 First, the statement, "If you build it, they will  
12 come," sounds great in the movies, but it isn't true in  
13 real life. It would be more accurate to say, "If the  
14 law requires it, they will come," or, "If they can't  
15 compete without it, they will come."

16           Simply having a well-written and thorough  
17 specification, which we did in blood banking, and  
18 having that specification available, does not guarantee  
19 that it's going to be adopted.

20           Second, we learned that technology is  
21 advancing today faster than most formal groups can make  
22 decisions about its use.

1 Third, we confirmed what everybody already  
2 knows: Barcodes reduce errors. They're fast, they're  
3 accurate, and they're easy to use. The case for the  
4 use of barcodes or other means of auto-ID is a  
5 compelling one.

6 Fourth, and most importantly in my view, we  
7 learned the importance of formally agreed-upon data  
8 structures as opposed to symbology standards. I think  
9 the approach that we used in the development of  
10 ISBT-128 was an effective one.

11 It involved the cooperation of all the  
12 stakeholders -- blood banks, transfusion services,  
13 hospitals, software providers, instrument suppliers,  
14 the barcode community, and the FDA. The only thing we  
15 lacked was the regulatory impetus for the change to be  
16 made.

17 Based on that experience with ISBT-128, we  
18 would make the following recommendations to the  
19 industry and to the FDA.

20 First, the FDA should require the use of  
21 machine-readable symbols on all human drug and biologic  
22 products. Eye-readable representation of significant

1 information should always accompany the machine-  
2 readable symbols.

3 Two, rather than require a specific barcode  
4 symbology or barcode language, the FDA should mandate  
5 that an agreed-upon data structure be encoded for  
6 machine reading. Were existing standards are  
7 available, such as ISBT-128, their use should be  
8 required.

9 Third, guidelines should be provided by the  
10 FDA to each stakeholder industry group which outline  
11 the minimum information content of the symbols and the  
12 timeline for implementation.

13 Finally, an auto-ID coordinating council,  
14 perhaps made up of some of the wonderful industry and  
15 regulatory groups that have been mentioned this  
16 afternoon and this morning. That auto-ID coordinating  
17 council should be appointed to help resolve  
18 implementation issues.

19 It would be made up of volunteers from the  
20 disciplines involved in the new requirements, barcode  
21 suppliers, and the FDA. It would be charged with  
22 ensuring that minimum information requirements are met.

1 It would be charged with maintenance of databases and  
2 the assignment of code structures; charged with making  
3 sure that the best technology available is used, and  
4 that costs to the individual institutions are  
5 minimized. Thank you.

6 MR. RITCHIE: My name is Bruce Ritchie. I'm a  
7 hematologist, a hemophilia treater, and I represent the  
8 Canadian Hemophilia Society and the Association of  
9 Hemophilia Clinic Directors in Canada. We also  
10 discussed the issue of barcoding in depth with Health  
11 Canada, and also with the National Hemophilia  
12 Foundation here in the U.S.

13 What I'd like to start out with is to say that  
14 machine-readable labeling of pharmaceuticals is clearly  
15 something whose time has come. And I think we have  
16 heard that today from many, many different people. And  
17 I applaud the FDA for moving this process forward with  
18 this public meeting. I think it's very important.

19 The FDA must be aware, however, that other  
20 regulators are interested in a global standard and are  
21 watching to see what the FDA does. I know the  
22 Europeans have been waiting to see what the outcome o

1 this and other meetings are before proceeding with  
2 standardization there in Europe.

3           Given the success of harmonization in the  
4 application for licensure of drugs, I think the FDA  
5 should consider harmonization of standardized machine-  
6 readable labeling, in particular standardization of the  
7 drug identifier, such as the NDC or the GTIN. I know  
8 the NDC information can be included in the GTIN  
9 standard that's been set by the UCC council.

10           As everyone else has said, I believe labeling  
11 of medicines is a safety issue. Everyone involved in  
12 the production, distribution, prescription, and use of  
13 medicines is responsible, either legally or otherwise,  
14 for tracking pharmaceuticals, for monitoring adverse  
15 events, and for recall of drugs.

16           So all the players must be able to tell  
17 exactly what's in the medicine package and record this  
18 information quickly and accurately, and that's where  
19 machine-readable labels or barcodes comes in.

20           Machine-readable labels such as barcodes offer  
21 dramatically improved speed and accuracy of data input,  
22 and will therefore foster the use of database tools

1 which are useful to track drugs, to record and report  
2 adverse events as they occur, and to aid in recalls.

3 In Canada, we've developed a national database  
4 program called CHARMS, which we use for tracking all  
5 blood coagulation products. And when recalls happen,  
6 and they happen all too frequently, we in the  
7 hemophilia clinics know exactly where the products are.  
8 These products are stored in patients' homes in large  
9 inventories, which is always a surprise to the  
10 governments who are funding these drugs in Canada.

11 So by setting standards of machine-readable  
12 labels, the FDA will allow everyone to track these  
13 products. And they will encourage drug prescribers,  
14 pharmacies, clinics, and users to use this data, and  
15 everyone will use this data. I know of three  
16 pharmaceutical companies who are setting up global Palm  
17 Pilot-based systems for patients to use in maintaining  
18 their inventory at home and recording their use of  
19 coagulation blood products.

20 Therefore, the simple philosophy that should guide  
21 this process is, apply the machine-readable label, such  
22 as a barcode, at the source because that's the easiest,

1 cheapest, and most accurate way to do it. And use a  
2 barcode that everyone can use. This means setting a  
3 standard for data format now.

4 And secondly, establishing a harmonized  
5 process to set standards for machine-readable systems  
6 now and in the future. As everyone has alluded to, the  
7 technology is changing, so we should have a process in  
8 place to set standards not only for the present, for  
9 today, for barcodes today, but for radio frequency  
10 chips for tomorrow.

11 In summary, I think the FDA should think  
12 separately about the data format and the way data is  
13 transmitted. The FDA should standardize the data  
14 format quickly, and allow manufacturers to add new  
15 technologies, meaning new standards for each new  
16 technology, to promote a widespread usefulness of this  
17 system.

18 The FDA should think carefully about setting a  
19 harmonized standard for data format and machine-  
20 readable technologies, a widely usable barcode for  
21 today, and standardized emerging technologies in the  
22 future. Thank you.

1           MR. STEANE: My name is Edwin Steane, and I'm  
2 with ICCBBA. ICCBBA is the group that was alluded to  
3 earlier by Kay Gregory as those that maintain and  
4 extend the ISBT-128 standard.

5           Bruce has already told you that the initial  
6 proposal for the ISBT-128 standard was in 1989. I  
7 would point out that it took five years to write that  
8 specification. None of this happens as quickly as you  
9 think it might, not if you're going to do what we did,  
10 which is to adopt three rules: Do it once. Do it  
11 right. Do it internationally.

12           We also had another rule that we displayed  
13 prominently: Never forget the law of intended  
14 consequences. You can do this as quickly as you want,  
15 but if you don't put the appropriate thought into it,  
16 it's going to fail.

17           As Bruce said, and as Kay said, if you build  
18 it, they will not come. The mandate that is needed fro  
19 the FDA is the use of machine-readable symbols in  
20 therapeutic settings wherever possible. Putting them  
21 on products and not requiring that they be used is a  
22 waste of time. What's needed is absolute insistence

1 that they be used. The goal should be the elimination  
2 of data entry by humans, whether it be through a  
3 keyboard or in written notes.

4 I would like to emphasize once again that the  
5 FDA should concentrate on data structures. They should  
6 not mandate technology. And the Dick Tracy radio  
7 frequency tag, by the way, is already available as part  
8 of a linear barcode on a blood group label. No one  
9 uses it, but it's already available. It's too  
10 expensive, of course.

11 So the emphasis should be placed on the data  
12 structure, not the means of capturing the data. The  
13 industry will look after that very well if you leave it  
14 to them.

15 So what should be in the data structures? I  
16 would suggest that the FDA can apply a very simple  
17 rule. If they require you to capture and record that  
18 information, then there should be a standard format in  
19 which that information is to be captured. And then  
20 putting those into machine-readable symbols becomes  
21 relatively simple.

22 Barcoding by itself, although a lot of people

1 in this room don't want to hear me say this because  
2 they want to tell you how difficult it is and how  
3 complex it is, is trivial. It's the consensus that's  
4 needed in order to be able to make the system work that  
5 is difficult.

6 Also, the information which is encoded and  
7 which appears on a label that an end user is to use  
8 should be the information that is of importance to the  
9 end user. And you should get everything else off that  
10 label because all it does is interfere with what the  
11 end user should be concentrating upon.

12 I would suggest to the hospitals, and I've  
13 listened to them with care, that if they really want to  
14 do something to make this system move, they all need to  
15 sit down and talk about a standardized way to identify  
16 the patient. And once you do that and the products are  
17 barcoded, the errors will go away. Thank you.

18 MR. MAYBERRY: Yes, hi. My name is Peter  
19 Mayberry, and I am the executive director for the  
20 Healthcare Compliance Packaging Council, which is a  
21 not-for-profit trade association founded in 1990 to  
22 promote the many benefits of unit dose blister and

1 strip packaging.

2           The HCPC is submitting formal responses to all  
3 the questions raised by FDA in the Federal Register  
4 notice announcing this meeting, but my purpose today is  
5 to underscore one primary point in our responses, and  
6 that is that the Institute of Medicine report on which  
7 a large part of this effort is based called for  
8 recommendations not only for barcoding but for unit  
9 dose packaging.

10           And I know you've heard quite a bit of  
11 difference between unit of use versus unit dose, but I  
12 think Dr. Cohen summed it up very, very well by saying  
13 a unit of use can be a container with 30, 60, 90  
14 tablets -- it's basically an entire course of  
15 regimen -- whereas a unit dose is a single dosage unit.

16           Specifically, on pages 166 through 167 of the  
17 1999 report, "To Err Is Human," IOM notes that, "If  
18 medications are not packaged in single dosages by the  
19 manufacturer, they should be prepared in unit doses by  
20 the central pharmacy." The report justifies this  
21 recommendation by noting that, "Unit dosing reduces  
22 handling as well as the chance of calculation and

1 mixing errors."

2           But the IOM also sounded an ominous alert in  
3 this section of the report by pointing out that, "Unit  
4 dosing was a major systems change that significantly  
5 reduced dosing errors when it was introduced more than  
6 20 years ago. Unfortunately, some hospitals have  
7 recently returned to bulk dosing as a cost-cutting  
8 measure, which means that an increase in dosing errors  
9 is bound to occur."

10           Indeed, in the time since the IOM report was  
11 first released, the HCPC has heard a growing number of  
12 anecdotal reports that pharmaceutical manufacturers are  
13 dropping the number of products offered in hospital  
14 unit dose or HUD formats. And as recently as May 15th  
15 this year, one pharmaceutical manufacturer noted during  
16 our national symposium on patient compliance that his  
17 company had deleted HUD formats for some 80 percent of  
18 their entire drug stock over the past two years.

19           Why are they doing this? According to the  
20 pharmaceutical manufacturers, because the hospitals are  
21 not purchasing HUDs because they're cheaper to buy them  
22 in bulk, just as IOM said.

1           So as FDA considers the user of barcodes as a  
2 mandatory requirement, the HCPC recommends that you  
3 consider a requirement that the barcode be placed at  
4 the unit level. In other words, every single dose of  
5 medicine has a barcode on it. The technology is there,  
6 and the requirement would be there such that the  
7 manufacturer would then have the obligation of  
8 providing medications which are intended for dispensing  
9 at inpatient settings. Each individual dosage would  
10 have a barcode on it.

11           And that would be about the only way that the  
12 IOM and the other organizations that have weighed in on  
13 this, as well as the practices of many other countries  
14 around the world, you would be able to achieve the  
15 degree of safety to which you're seeking. That's my  
16 primary point for the afternoon.

17           MR. POLINSKY: I'm Steven Polinsky. I am with  
18 GenuOne Corporation, and we provide pharmaceutical  
19 manufacturers and biological product manufacturers with  
20 enhancements that are technology-based against  
21 counterfeiting and parallel trade. So we do a lot with  
22 barcoding and other marketing.

1           Our solutions include unique machine-readable  
2 authentication that can be integrated directly into  
3 existing barcodes and other packaging mediums. Also,  
4 we enable pharmaceutical manufacturers to print  
5 barcodes that are invisible to the human eye. The  
6 reason that this is necessary is in the parallel trade  
7 and gray market business, gray marketers tend to deface  
8 product packaging. So we have to stay one step ahead  
9 of these folks with our manufacturers.

10           And it came up today, but it was asked, what  
11 other data elements should be considered when putting  
12 together some type of barcode standard. And it's very  
13 clear to me it should be machine-readable  
14 authentication, and the reason being that \$12 billion  
15 annually of counterfeit medications find their way into  
16 hospitals, and especially biological products over the  
17 past 18 months have been very hard hit because these  
18 drugs are high-priced and have high margins.

19           And the result obviously can be illness and  
20 even death. And the bottom line is, even if a  
21 counterfeit drug is administered properly, the result  
22 can be adverse and be the same. So it's up to the FDA

1 to provide a cost of scale to manufacturers when they  
2 build the solution to address both of these issues  
3 together.

4           Although the authentication technology is much  
5 more sophisticated than barcoding -- barcoding is  
6 actually rather simple -- implementation and  
7 integration of an authentication mark that's a unique  
8 signature that's machine-readable is actually fairly  
9 simple. It can be directly put into the ink. It can  
10 be into the dye that's actually printed when they print  
11 the barcode, the manufacturers, onto a particular box.  
12 So it's inherent in what they're doing already.

13           We actually have a lot of clients that are  
14 doing this, so they're already providing not only  
15 barcoding, but it might be invisible so they can't be  
16 human-readable. It can be scanned and it can provide a  
17 unique authentication to stay one step and raise the  
18 bar on counterfeiters that are out there as well.

19           Scanners can also be retrofitted or calibrated  
20 to be able to read these unique marks as they are  
21 reading barcoding informatics as well. And this  
22 addition to your standard will help mitigate what I

1 believe, and a lot of other people feel, is a major  
2 patient safety issue, probably the other big one.  
3 That's consumption of counterfeit drugs. Thank you.

4 MR. SCHWARTZ: My name is Robert Schwartz and  
5 I'm chairman of the board of the Healthcare  
6 Distribution Management Association.

7 HDMA is a national trade association  
8 representing pharmaceutical and related healthcare  
9 product distribution in the United States. HDMA's  
10 distributor members operate over 260 distribution  
11 centers nationwide and provide products and services to  
12 approximately 120,000 pharmacy settings, including  
13 independent, chain, hospital, mail order, mass  
14 merchandisers, food stores, long-term care, home health  
15 facilities, clinics, and HMOs. HCMA also represents  
16 over 220 pharmaceutical manufacturer companies who  
17 distribute prescription products from hundreds of  
18 facilities.

19 HDMA's mission is to secure the safe and  
20 effective distribution of healthcare products across  
21 the supply chain from point of manufacture to point of  
22 administration.

1 HDMA is supportive of efforts to utilize  
2 barcodes at the unit of use level of all drug and  
3 biologic products as part of an initiative to reduce  
4 medication errors. We appreciate the caution that FDA  
5 has exhibited in this process, and welcome the  
6 opportunity to work with the agency and other  
7 stakeholders to ensure that our efforts enhance patient  
8 safety without an undue economic impact to the industry  
9 and risk of disruption of the supply of drugs through  
10 the healthcare system.

11 HDMA supports barcode labeling for all  
12 prescription drugs and vaccines supplied for  
13 administration to patients in hospital or institutional  
14 settings. We believe this would address the vast  
15 majority of critical medication error issues.

16 However, there is no current evidence that  
17 this would be so in retail or other treatment settings.  
18 To require barcodes on all products in all settings  
19 during the initial phase of any forthcoming FDA mandate  
20 would greatly add to the costs of barcode labeling  
21 implementation and substantially slow the process,  
22 causing possible delays in reducing medication errors

1 that are readily avoidable in the near term with  
2 current standards and technology.

3 HDMA supports the use of the National Drug  
4 Code in any barcode application. The NDC is a standard  
5 identifier with a unique, all-numeric system  
6 identifying the pharmaceutical manufacturer or  
7 distributor, drug product, and package size.

8 It is widely used by manufacturers and  
9 distributors throughout the industry, and is already  
10 required by FDA regulation. Product and dose  
11 information which is included in the NDC number is  
12 critical for preventing administration of the wrong  
13 medication of strength.

14 HDMA is not aware of any current data  
15 demonstrating that the inclusion of secondary  
16 information such as lot number and expiration date in a  
17 barcode will reduce medical errors. We do not believe  
18 that including such information in a barcode at this  
19 time will have a noticeable effect on FDA and the  
20 industry's goal of medication error reduction.

21 It is our opinion that this information is not  
22 critical bedside scanning in order to screen for

1 medication error. Screening for out-of-date or  
2 recalled medications should not be performed at the  
3 bedside and therefore is not needed in the unit of use  
4 barcode.

5           Consequently, HDMA discourages FDA from adding  
6 auxiliary information such as lot number and expiration  
7 date to the first requirements for barcode usage.  
8 Under FDA's current charge to reduce medication errors,  
9 especially at the unit of use bedside level, such  
10 information is not essential at this time, and  
11 inclusion would only add to the costs and complexity of  
12 implementation.

13           HDMA does not believe the agency should  
14 specify a single barcode symbology and require its use  
15 at this time. If FDA limits the healthcare community  
16 to a single symbology, it will significantly reduce our  
17 ability to comply quickly since more work will need to  
18 be done for the industry to adapt.

19           In addition, HDMA finds that two-dimensional  
20 symbology is not currently required to meet the goals  
21 of error reduction. A linear barcode for the NDC  
22 number, supplying product and dosage information, will

1 address the vast majority of medication errors without  
2 the need to render entire systems obsolete.

3           The requirement of 2D symbology will add  
4 considerable expense and time delays to the supply  
5 chain while the industry invests in this still-  
6 developing technology. The mandatory use of barcodes  
7 will have a significant economic impact on the  
8 industry, especially manufacturers and distributors  
9 that will be required to invest in packaging  
10 technology, equipment components, computer systems for  
11 integration, and implementation costs across the supply  
12 chain.

13           FDA should not mandate a particular location  
14 for the barcode on all products. Variations in size,  
15 shape, and packaging will make consistency next to  
16 impossible, particularly when viewed in light of the  
17 regulated information and presentation already required  
18 for medical product labeling.

19           Instead, HDMA recommends that guidelines be  
20 offered requiring barcode placement in a way that is  
21 fully scannable, especially on small or rounded  
22 products. It is far more important to ensure that the

1 barcode is placed in a location where it may be scanned  
2 instead of being in a particular location. Thank you.

3 MR. COLLINS: My name is David Collins. I am  
4 the president of Data Capture Institute. And our  
5 activity centers around the expert development of  
6 architectural systems where barcode or auto-ID is a  
7 driving influence to the information technology in  
8 large enterprises.

9 I'm here to make a recommendation, and the  
10 recommendation goes to the heart of controlling the  
11 complex, long-life assets used in providing or  
12 delivering healthcare. I don't think the position  
13 taken earlier today by a panelist saying, forget the  
14 medical devices category because you can't justify  
15 labeling on a tongue depressor, makes any sense at all.

16  
17 There are complex delivery systems used in  
18 healthcare. Healthcare is an asset-intensive industry.  
19 And they are going without supervision, largely, and  
20 primarily because those manufacturers who are  
21 delivering these systems don't have a standard format  
22 for expressing who the manufacturer is and what that

1 serial number related to the manufacturer is in a  
2 format that can be recognized universally, even though  
3 one format exists and serves that purpose.

4           The format we recommend is the EAN/UCC global  
5 individual asset identifier. It's been available since  
6 1995, and it has three principal fields of information.  
7 The first field is a message indicator that says, I am  
8 an asset and I should be monitored. The second field  
9 of information gives the manufacturer identification.  
10 The third field of information expresses the serial  
11 number assigned by that manufacturer in whatever format  
12 the manufacturer desires. It's that simple.

13           Since it's an EAN/UCC standard, it's available  
14 for creation of information and support anywhere in the  
15 world. And as far as the cost to the label is  
16 concerned, this on my fingertip, instead of a 30-foot-  
17 long label in a slide, represents such a label. And  
18 the cost would be, nominally, five cents.

19           With that label in play, if you will, in the  
20 healthcare community, you will find many software  
21 providers coming forward with software applications  
22 that will allow you to very easily drive a system to

1 monitor assets. That gives you product ownership and  
2 stewardship from creation to current use. It gives you  
3 in-service history. It gives you repair history,  
4 warranty information, reclaimability for recall, and  
5 many other features I don't have the time to cover.

6 But it has a precedent being mandated in the  
7 federal government today. The FAA adopted this marking  
8 systems for suppliers of air traffic control systems in  
9 1998, and to date over \$2 billion of equipment has been  
10 placed on order, and about half of that equipment  
11 already delivered, bearing this unique identification  
12 which allows the traceability. You might say they're  
13 in the healthcare industry as well.

14 With the proper use of this on medical  
15 devices, medical devices will always be assigned to the  
16 appropriate patient. After patient use, the reusable  
17 medical devices will be properly cleaned. Medical  
18 devices requiring recalibration will have an audit  
19 trail to ensure that this has been done.

20 These assets will be visible through a  
21 database screen or a browser, and they will be shown in  
22 all their assigned locations. And linking the

1 medication provided to these devices through the  
2 methodologies described in most of this conference can  
3 be easily accomplished to give one more level of  
4 security in healthcare delivery. Thank you.

5 MR. ASHBY: My name is Daniel Ashby. I'm  
6 director of pharmacy at Johns Hopkins Hospital, and  
7 also associate professor at the School of Pharmacy for  
8 the University of Maryland. I'm pleased to be here  
9 today to offer comments concerning the needs and value  
10 of barcodes, maybe from the perspective of a hospital  
11 and a department of pharmacy.

12 I wanted to share two stories with our panel.  
13 I'm now part of an organization that finds itself on  
14 the front page of the Baltimore Sun and other  
15 publications on a pretty regular basis.

16 Sometimes that's a source of pride. Those  
17 articles often reflect accomplishments. Sometimes  
18 they're accomplishments that reflect what's happening  
19 in hospitals all across the country and the efforts  
20 healthcare providers everywhere make on behalf of  
21 patients in America.

22 Sometimes it's a source of frustration. When

1 we learn that we didn't receive a notice for a recall  
2 for a bronchoscope, when we realize that we didn't get  
3 the job done, when we realize that patient harm  
4 resulted because of that, it creates some real  
5 concerns.

6 That event drove us to look at the recall  
7 procedure for everything we did in the hospital. From  
8 a pharmacy standpoint, I was surprised. There are  
9 hundreds of recalls every month. Sometimes it's a  
10 capital S versus a small S. That turns into thousands  
11 of line items sometimes. It turns into 200 areas that  
12 we have to check.

13 Our conclusion was, we did a pretty good job.  
14 We thought we usually got the notice. We thought we  
15 usually checked all the areas. Well, we usually  
16 checked most of the areas. We usually documented that  
17 check.

18 Usually isn't good enough. Barcode technology  
19 would help. Did we order it? Did we receive it? And  
20 where did we ship it to? I don't disagree, we wouldn't  
21 do this at the bedside. We would, however, do it at a  
22 single unit of use package level.

1           When you distribute the drug to the hospital,  
2 you put a hundred doses in a bin. To check them, you  
3 have to check them one at a time visually. There is no  
4 job more boring in a hospital than checking for expired  
5 drugs on the unit. Barcode technology clearly could  
6 improve the process and improve the safety of  
7 medication use system.

8           A second story I'd share with you: The  
9 Department of Pharmacy at Hopkins dispenses 15,000  
10 doses or more every day. We've been working hard to  
11 decrease the number and percentage of missing doses  
12 that occur.

13           We've made progress. We've decreased that  
14 percentage from 1.7 to 1.3 percent over the last  
15 several months, a 25 percent improvement. That's the  
16 good news. However, the bad news is we still have 195  
17 missing doses every day. It causes delays,  
18 interruptions, and the potential for error.

19           I found it interesting, thinking back last  
20 week, that I can send a package to my Peace Corps  
21 volunteer son in Honduras, and I can check online to  
22 see where that package is. On the other hand, when we

1 get a call from a nurse asking where a dose of a  
2 critically needed medication is, we don't know. We'll  
3 be happy to send you another one. Do we ever stop to  
4 wonder what happened to the other dose and where it  
5 went? Clearly, barcode technology can help with this  
6 also.

7           To our colleagues in the pharmaceutical  
8 industry, we realize this isn't as simple, maybe, as  
9 everyone makes it seem. We use the example that we can  
10 buy a loaf of bread in the grocery store. If we can do  
11 it there, why can't we do it in healthcare? The  
12 challenge is more difficult. We want you to wrap each  
13 slice individually, and we want you to barcode that  
14 slice.

15           The reality, too, though is this isn't new  
16 technology. The concept of unit dose is almost as old  
17 as mountains. Barcode technology, on the other hand,  
18 has been around a long time, too. Group purchasing  
19 organizations, ASHP, and associations for years have  
20 said, this is the standard. This is the direction we  
21 ought to be going to. What you're hearing today  
22 shouldn't be a revelation.

1           Two to three years is not acceptable. I'd  
2 offer the following four recommendations.

3           In terms of which products should carry  
4 barcodes, drug manufacturers should provide all  
5 prescription and over-the-counter drugs in barcode  
6 packages down to a single unit of dose level.

7           In terms of the information to be provided,  
8 clearly the drug identifier, name, strength, and unit  
9 needs to be there. But we also need the lot number for  
10 recall purposes and the expiration date to prevent the  
11 utilization of expired medications.

12           In terms of where the barcode needs to be  
13 placed on the package that's going to be used by the  
14 patient, if you market a drug in America, you must  
15 provide a unit dose or unit of use package.

16           In terms of when, as soon as humanly possible.  
17 Two to three years is not acceptable. We haven't been  
18 successful with a voluntary effort. We haven't been  
19 successful with market forces. Winston Churchill is  
20 attributed to have said, "We can always count on  
21 Americans to do the right thing, but only after they've  
22 exhausted all the other options."

1 (Laughter)

2 A mandate from the FDA is clearly needed at  
3 this time. Thank you.

4 MR. BARENBURG: Good afternoon. My name is  
5 Ron Barenburg, senior vice president of Barcode  
6 Technology, Incorporated, or BTI. Some of you may know  
7 us as International Barcode, which is our prior name.

8 BTI specializes in providing barcode software  
9 and hardware solutions. Through our subsidiary S&X, we  
10 have provided and serviced Barcode Pro software to over  
11 120,000 clients worldwide over the past 13 years. Our  
12 offices are located in New York City and Coral Gables,  
13 Florida.

14 Thank you for giving BTI an opportunity to  
15 address the FDA and the healthcare community on the  
16 need for expert information concerning reduced space  
17 symbology barcodes. This family of barcodes can encode  
18 the NDC, or NDC, lot, and expiration date, on various  
19 packaging levels of prescribed an/or over-the-counter  
20 medications.

21 Ladies and gentlemen, over the past one and a  
22 half years, I have traveled well over 100,000 miles to

1 visit many of the pharmaceutical companies here today.  
2 Many of you are BTI's clients, and you are the true  
3 visionaries.

4           You've not only seen the value of reduced  
5 space symbology as an asset in improving patient  
6 safety, but as a significant tool for product control  
7 and traceability.

8           In August of 2001, under the guidance of the  
9 Uniform Code Council, BTI software provided the RSS  
10 barcode graphics Abbott Laboratories used to print  
11 labels on small vials and ampules. These RSS NDC  
12 labels were then scanned at bedside at St. Alexis  
13 Hospital in Bismarck, North Dakota. This was one of  
14 the first successful pilots of RSS on small unit dose.

15           Since that time, we've come a long way. Two  
16 days ago, on July 24th, Abbott Laboratories announced  
17 that they pledge to affix unit of use barcodes to all  
18 of its hospital injectable pharmaceuticals and IV  
19 solutions product lines by early 2003.

20           RSS is currently in use by other companies in  
21 the healthcare industry. Its small size, powerful  
22 encoding capabilities, and human-readable formats make

1 it ideal to print machine-readable information on unit  
2 dose, over-the-counter, and prescribed medications.  
3 And it is part of the global UCC/EAN family of  
4 barcodes, ensuring worldwide acceptance and use.

5 As its full potential is realized, RSS will  
6 also be a solution for encoding information to aid in  
7 record tracking and to provide portable databases on  
8 medical, surgical, and blood products. RSS barcode can  
9 replace the human-readables currently preprinted on  
10 labels with a minimum of effort and cost, encoding the  
11 NDC number with accompanying human-readables.

12 As for the critical step of placing lot number  
13 and expiration dates on products in realtime on the  
14 manufacturing line, BTI and its strategic alliance  
15 partners, Domino Amjet and Zebra Technologies, have  
16 already demonstrated the capability of inkjet and  
17 thermal inline printing at line speeds, with laser  
18 printing in the near future.

19 Verification prior to webscan: Another BTI  
20 strategic alliance partner has off-the-shelf and  
21 readily available verifiers to provide ANSI-grade  
22 reports on RSS-generated barcodes.

1           Symbol and handheld scanners have both  
2 announced substantial sales of RSS-enabled scanners,  
3 which can also read all the current symbologies in use  
4 by healthcare today. Just as important is the RSS  
5 upgrade methods available for existing scanners.

6           This should provide a comfort level that when  
7 pharmaceutical companies encode information in RSS to  
8 reduce medical errors, end users can have scanners that  
9 are available to read that information.

10           We look to the FDA for the following:

11           First, to establish a barcode symbology  
12 standard like RSS that has software that is readily  
13 available and in use by healthcare today, a barcode  
14 that is easily scanned by off-the-shelf, readily  
15 available scanners.

16           Second, to provide for an aggressive but  
17 realistic time frame for adoption of this barcoding  
18 requirement.

19           And third, to establish minimum machine-  
20 readable information requirements with implementation  
21 of NDC, lot, and expiration date as the fastest  
22 timetable.

1           But let us not forget the larger purpose of  
2 our work here today. Machine-readable barcoding  
3 information and global standardization will save lives.  
4 Thank you.

5           MR. SNIPES: I'm Billy Snipes, executive vice  
6 president of Returns Online, Incorporated. Our company  
7 provides comprehensive recall management services to  
8 manufacturers, distributors, and retail entities of  
9 pharmaceutical and medical device products.

10           I'm also a pharmacist, and for the last 15  
11 years have been involved in the pharmaceutical returns  
12 industry and recall industry. We've handled hundreds  
13 of thousands of returned pharmaceutical products, and  
14 hundreds of thousands of recalled pharmaceutical  
15 products. Therefore, I'd like to direct my statement  
16 this afternoon regarding the recall end of the spectrum  
17 and how I think the safety of the patient could be  
18 enhanced there.

19           Returns Online commends and supports the  
20 development of a regulation on barcode labeling for  
21 human drug products and medical devices for the  
22 following reasons:

**Diversified Reporting Services, Inc.**  
1101 Sixteenth Street, NW Second Floor  
Washington, DC 20036  
(202) 467-9200

1           Any human drug product or medical device that  
2 will be administered or dispensed to the public should  
3 contain a barcode that identifies the drug product  
4 through the NDC, the lot number of the batch, and the  
5 expiration date of the product. To enforce this  
6 stance, let's consider how accuracy and patient safety  
7 could be improved in the distribution of the product,  
8 the dispensing of the product, and if necessary, the  
9 recall of the product.

10           The manufacturer and/or distributor would have  
11 the ability to scan the barcode to immediately indicate  
12 the lot number and expiration date that it is shipping  
13 to an entity, either a retailer or another distributor,  
14 and begin the building of a database that would track  
15 that drug from either the manufacturer or the  
16 distributor to the next step. This database has been  
17 mentioned several times today on trackability. How can  
18 we track that product all the way?

19           The pharmacist, on the other hand, would be  
20 able to scan that bottle or that container and capture  
21 that lot number, along with the identification of the  
22 product, and further enhance that database. It's now

1 gone from the manufacturer to the distributor to the  
2 dispenser.

3           When he dispenses the medication to the  
4 public, he would also scan that. It was mentioned  
5 earlier that several states had mandated the lot number  
6 be put on the label of prescription drugs, and a lot of  
7 that, I think, went away because lot numbers are hard  
8 to capture manually.

9           They are up to ten characters long, either  
10 alpha or numeric. Some of them are stamped on the top  
11 of the boxes and are really hard to read. o the  
12 barcoding of a lot number onto a container would make  
13 it much easier to continue that tracking process.

14           Both the distribution and pharmacy software  
15 should have the able to carry a database of previously  
16 recalled products. If you had previously recalled lot  
17 numbers listed under NDC numbers in a database upon  
18 dispensing or distributing, and you scanned that  
19 barcode on the container that you're utilizing, if it  
20 had been recalled in the past, that would be an  
21 automatic flag that that doesn't need to go out. I  
22 think the gentleman before me talked about that

1 happening.

2           And a recall is a one-time event for lot  
3 number, and specifically. And if it's missed on the  
4 shelf, either in the pharmacy or in the distribution  
5 center -- because about the only way we've got now is  
6 just to go manually look for it. Some of them are  
7 missed and some of them are utilized later.

8           It's understood that some of these things  
9 could be done by manually entering these lot numbers  
10 rather than utilizing the scanner and the barcode  
11 technology. However, as I mentioned before, those lot  
12 numbers are hard to read.

13           In conclusion, there are a number of far-  
14 reaching benefits to expanding current barcode labeling  
15 requirements for pharmaceutical and medical devices as  
16 it pertains to safety recall management specifically,  
17 the accuracy and time efficiencies to monitor and  
18 assess the effectiveness of a recall event, and come up  
19 with the recall effectiveness.

20           Additionally, automation in the distribution  
21 and dispensing level can improve the identification and  
22 segregation of recalled product to prevent further

1 distribution, and safeguarding the public against the  
2 dangers of receiving outdated and recalled product.

3 Dr. Feigal, I think, mentioned several times  
4 the trackability. One of those was that out of a  
5 thousand to 1400 medical device recalls last year,  
6 sometimes only 5 percent of the recalled product was in  
7 hand or gotten back.

8 If we had the ability to track that through  
9 the lot number and the databases that we could build in  
10 distribution, I think we'd be a lot better off. Thank  
11 you.

12 MR. HANCOCK: My name is Ed Hancock. I'm  
13 president of American Health Packaging. American  
14 Health Packaging is a packaging subsidiary of  
15 Amerisource Bergen Corporation, the largest  
16 pharmaceutical distributor in the United States.

17 We are a full-service packaging provider,  
18 offering pharmaceuticals repackaged under the American  
19 Health Packaging label, as well as packaged under  
20 contract to manufacturers under their label. We're  
21 organized to provide packaging needs to the end users  
22 and retail institutional markets, as well as to the

1 manufacturers themselves.

2           Types of packaging that we utilize include  
3 bottles, unit dose blisters, and pouches, utilizing the  
4 same processes as do the manufacturers themselves. And  
5 we also offer pharmaceuticals also packaged in other  
6 unit dose formats such as vials, prefilled syringes, et  
7 cetera, applying barcodes to those packages.

8           For the sake of time, I'll confine my brief  
9 comments to making two points out of the full comments  
10 I made to the docket. One is about barcode content,  
11 the other about barcoded package availability.

12           Regarding barcode content, product and dose  
13 information is critical for preventing administration  
14 of the wrong medication or strength. Other information  
15 may be useful and may present opportunities for other  
16 medication safety activities, but it's not critical to  
17 bedside scanning, effectively screening for medication  
18 error.

19           The NDC number of a medication is specific to  
20 the medication and dose and manufacturer. And since it  
21 is available extensively on medication packages today,  
22 it makes the most sense to use rather than add any

1 other unique code to the package. The NDC is already  
2 the most common barcoded information in pharmaceutical  
3 packages, as has been stated.

4 Other information considered, like package  
5 type or lot and expiration date, are needed in  
6 pharmacies for inventory control purposes, but not add  
7 significant benefit to bedside scanning. Screening for  
8 out-of-date or recalled medications, as stated before,  
9 should not be left to deal with at the bedside.

10 These matters are critically important, but  
11 must be dealt with effectively prior to the medications  
12 reaching the patient. To regulate barcode content for  
13 purposes other than bedside scanning risk adding  
14 unnecessary complexity, which can deter implementation.

15  
16 The recommendation then is to require the NDC  
17 only for the smallest administered dose level. In most  
18 cases, that is the unit dose.

19 As a repackager of pharmaceuticals, we've  
20 initiated applying barcoded information on all types of  
21 packaging for all end use markets. Most major  
22 repackagers in the United States have made similar

1 decisions, and apply barcodes to the dose level for  
2 unit dose package on pharmaceuticals packaged under  
3 their label. A few have demonstrated the capability to  
4 apply various symbologies. That creates a source of  
5 barcoded packages for every setting where  
6 pharmaceuticals are dispensed to patients.

7           The predominant use for barcoded information  
8 today is for the inventory control in all settings,  
9 institution and retail. But a growing number of  
10 hospitals are launching bedside scanning initiatives,  
11 as we've heard, and are beginning to use the barcoded  
12 information applied to the unit dose packaging for that  
13 purpose.

14           In every case where that is happening today,  
15 the NDC number, and only the NDC number, is being used  
16 as the key information to prevent medication dispensing  
17 errors. As we understand it, this is the case at the  
18 Veterans Administration facilities reportedly holding  
19 the leadership position in these systems.

20           There are many potential uses of barcoded  
21 information, and many of them are potentially  
22 beneficial to the safety of patients. But all the

1 other uses are facilitated by activities somewhere  
2 other than at the bedside, where the most critical need  
3 is ensuring the patient is getting the medication  
4 prescribed.

5           There are other systems being developed,  
6 developed to address the potential for the physician to  
7 prescribe the wrong medication, or the prevention of  
8 errors in transcribing of prescriptions. All of these  
9 preventable systems must happen somewhere before the  
10 medication appears at the bedside in the hospital  
11 setting.

12           Speaking of availability, even though  
13 commercial repackagers today offer many products in  
14 unit dose formats for hospitals, many more could be  
15 made available with a decision to allow interpretation  
16 of the recent U.S. Pharmacopeia and National Formulary  
17 guidance as written.

18           The first supplement to USP 25-NF(20),  
19 effective April 1st, Packaging Practice: Repackaging of  
20 Solid Oral Drug Product in the Unit Dose Container,  
21 provides the capability of repackagers to establish a  
22 beyond-use state of up to 12 months for oral solid