U.S. Food and Drug Administration

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FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Drug Shortage Workshop

A Workshop Sponsored by

The Food and Drug Administration

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1 P R O C E E D I N G S

2 DR. COX: ...and then to comments from Dr.
3 Throckmorton, and then we'll move on, and we'll some
4 about the current status of drug shortages through a
5 series of presentation. Then we'll move to the
6 patient's perspective, the healthcare perspective, and
7 then we'll have a period of closing questions and
8 comments. And we would ask that people sign up, given
9 the size of the meeting, at the registration desk if
10 you'd like to make formal comments during the opening
11 comments and questions period.
12 After folks have had a chance to make formal
13 comments, then we'll move on and allow folks that want
14 to ask questions to also come up to the microphone and
15 do so.
16 After the morning questions and comments
17 period, in the afternoon we move to recommendations for
18 solutions to address drug shortages. We'll have a
19 panel discussion. The panel discussions will be
20 several in numbers, and they'll include discussion from
21 the healthcare professionals, supply chain, and then
22 also the pharmaceutical industry.

1 Then following those panels, we'll have
2 another period of open questions and comments. And
3 again, if you'd like to speak in the afternoon session
4 and make formal comments, we ask that you sign up out e
5 front at the registration desk, and that'll help us to
6 manage time and time allotted will be dependent upon
7 the number of folks that do sign up.
8 Just so folks know, the meeting is being
9 webcasted, so that folk who are aware. And then also,
10 there will be a transcript. We expect the transcript
11 will post about 30 days after the meeting along with
12 the slides too. We did try and make slide available,
13 but a large number folks and some of the slides,
14 including my own, were a little later coming in, so
15 they will be available on the Web site following the
16 meeting.
17 I expect as the day goes on too the room may
18 get a little more full with folks. We do have a couple
19 of overflow rooms toward the back, and the folks at the
20 registration desk can help folks find those rooms as
21 needed. We certainly did our best to accommodate
22 folks, but I think many have probably noticed, as we

1 all have, the increasing interest in drug shortage over
2 the last several months, and it exceeded the capacity
3 of what we originally planned when we started planning
4 this several months ago.
5 So I welcome everybody, and we look forward
6 to a productive day. And with that, I'll welcome Dr.
7 Douglas Throckmorton, Deputy Center Director for
8 Regulatory Programs to the podium to make some
9 introductory and welcoming remarks. Thanks, Doug.
10 DR. THROCKMORTON: Thanks very much, Ed. My
11 congratulations to the organizers. As you all know,
12 organizing and planning a meeting like this does not
13 happen quickly, but it arise at a very auspicious time
14 in this particular challenge. The issues around drug
15 shortage are at unprecedented levels of interest, and
16 this meeting occurs at a time when it has potential to
17 have maximal impact. The things you guys talk about
18 today can really make a difference, can really be fed
19 into things that are going on to try to alleviate this
20 serious shortage. I applaud the organizers for their
21 sense of timing as I said.
22 What I'd like to do today is talk very

1 briefly about the gravity of the current situation --
2 you're all are aware of that I'm quite certain -- some
3 of the reasons that may be behind the shortages these
4 things will be discussed in greater detail through the
5 day, and then lead with a conversation about the FDA
6 and its role in this larger picture in addressing the
7 drug shortage issue, and some comments about the goals.
8 So this is my only data slide. It makes two
9 points. One: Despite the efforts of all of the
10 partners in the room, and particularly the FDA, our
11 drug shortage issues are growing worst and not better.
12 The second point is that the shortages matter. They
13 are the injectables. They are the things that we
14 understand to be most important for public health. They
15 are things that we need to address or things we need to
16 find a way to turn around.
17 The reasons behind these trends are not hard
18 to find: Economic forces, industry consolidation,
19 manufacturing challenges such as manufacturing quality,
20 discontinuations, and capacity issues. All are playing
21 into a larger spectrum to causes drug shortages to grow
22 worst and not better.

1 The FDA's role first and foremost is to focus
2 on those products that are necessary to meet medical
3 needs of critically ill patients. Our priorities must
4 remain on the medically-necessary drugs. Within that
5 context, we're working with manufacturers, affected
6 patients, physician groups, any group that we can to
7 minimize the impact of those shortages through
8 information sharing wherever possible; and the group
9 has set up a complex net of communications that I know
10 has worked to alleviate shortages in the past. We've
11 obviously shown flexibility where we could around
12 manufacturing and review wherever that's possible, but
13 we are one group among many.
14 And there are others in the room that know
15 they also play an important role in addressing this
16 drug shortage issue. This list is a long one. You may
17 be able to add others. Manufacturers, distributors,
18 prescribers, professional societies, consumer groups,
19 academics, and payers all play a role in this issue,
20 all play a role in addressing the continuing shortage
21 issue.
22 The goals then of this workshop first and

1 foremost is to discuss our perspective, the FDA's
2 Center for Drug Evaluation and Research's perspective,
3 on how we have been working to alleviate and address
4 the drug shortage issue.
5 We need to learn from you in the room about
6 new ideas, new things that have not yet been tried, or
7 ways to make things that have be done better or more
8 efficient or more timely to find ways to address the
9 drug shortage issue. This critical need for important,
10 lifesaving medicines needs to be addressed by all of
11 us, not simply the FDA. We need to find solutions to
12 alleviate or prevent these drug shortages.
13 I'll summarize then by welcoming you. Thank
14 you for making the time to come here. This meeting is
15 occurring at an important time as I said. We will
16 listen very carefully, and the things that are
17 discussed here are timely and have real potential to
18 change the way we go forward.
19 We are seeking to identify new tools to
20 alleviate or prevent drug shortages not limited to the
21 things that the FDA can do. We thank all of you who
22 are participating and looking forward to working

1 together with you to address this problem.
2 Ed, thank you very much.
3 DR. COX: Thank you, Doug. Now I'd like to
4 invite Rear Admiral Sandra Kweder to the podium to
5 provide us with some comments and perspective on the
6 public health impact of drug shortages. Sandy.
7 DR. KWEDER: Good morning, everybody. I
8 really want to congratulate the Drug Shortage staff for
9 putting this meeting together this morning. These are
10 the folks who work on these shortages and try and
11 mitigate their impact every single day.
12 I'm here because I'm in the Office of New
13 Drugs, which is the office within which the drug
14 shortages team sits, but they don't work alone. We
15 have, as you already know, there are professionals from
16 every corner of FDA who try and work on this. But I
17 want to acknowledge, as Doug alluded to, that this is
18 not just a burden or a puzzle to piece together and fix
19 just for FDA or just for the Drug Shortage staff.
20 So let me just -- looking around the room,
21 raise your hand if you are here as a member of the
22 medical profession who sees patients or interfaces with

1 patient care on a regular basis. Just raise your hand,
2 the table and in the room.
3 Okay. So you see this drug shortage
4 challenge from a very up close and personal
5 perspective. You see the distress that it causes in
6 day-to-day operations of taking care of patients, of
7 being the patient whose fourth course of chemotherapy
8 is delayed or they have to accept a substitute that,
9 hmmm, maybe the oncologist isn't too sure about.
10 Raise your hand if you are here from the
11 pharmaceutical industry as a distributor or as a
12 producer. Anybody at the table?
13 Okay. So you're the folks who are out there
14 trying to figure out, "Okay, FDA is calling me. We got
15 to fix our facility, and you know we got these leaks
16 over in Building A, and we don't know what kind of
17 problems they're causing in Building B where we got
18 this product that's not so big, but we need to maintain
19 production because if not the oncologists and the
20 anesthesiologist are going to be screaming, and our
21 competitors are going to do really well, but I got one
22 facility."

1 Or you're trying to ramp up production
2 because FDA is calling you, and if you ramp up
3 production in one thing, it means you got to give up
4 something because you only have so much capacity. It's
5 a tough spot to be in.
6 My challenge to this group to and going
7 forward is -- the folks that have raised their hands
8 and then everybody else in the room who sees this from
9 another window all have the capacity to think about
10 these challenges and figure out -- we're all in this
11 together, okay. There's no one cause of this. We're
12 all in this, and we've got to look at ourselves and
13 figure out what can we do to prevent these. You know
14 what, we don't want to have a big drug shortages staff.
15 We will if we have to, but that's not our goal. We're
16 not into empire building on the drug shortages staff
17 here at FDA. We want this to not be a public health
18 problem. It is a public health problem, but it is
19 solvable, and there are many spheres of activity that
20 can contribute to addressing it. We want you to look
21 at yourself and what you can do to prevent it and how
22 you can partner with parties in your own sphere and

1 outside of it to try and prevent these shortages.
2 We have said from the beginning of this that
3 it is the responsibility of the pharmaceutical
4 industry, if you're in this business, to produce a high
5 quality product. When you go into this business,
6 that's your job. Okay. We're willing to help to do
7 that. Where we can facilitate that, we absolutely
8 will.
9 This isn't the industry's fault, but what we
10 all need to do -- and people outside this room whose
11 pay grades are way bigger than mine -- to also look at
12 what are the other influences that have gotten us to
13 this place today and how are those also being
14 addressed. So I challenge you to think creatively.
15 Think with a really opened mind. Look outside the view
16 that you usually have and try and understand this so
17 that our solutions can be creative and practical and
18 implementable in rapid order.
19 So thank you for being here, and I will look
20 forward to hearing the discussion.
21 DR. COX: Thank you, Sandy. Now I'll move on
22 and provide some perspectives on the CDER Drug Shortage

1 Program and some of what we've seen over the last
2 several years. I'll start out just with some
3 background on the CDER Drug Shortage Program and then
4 talk some about what we've seen with regards to the
5 trends in shortages; discuss some of different
6 categories of reasons for shortages that we've seen;
7 talk some about industry's role; and then also discuss
8 CDER's role and approaches to prevention and mitigation
9 of drug shortages.
10 And when I speak about drugs, generally I'm
11 talking about drugs, therapeutic proteins, and
12 monoclonal antibodies. There are the products that are
13 regulated within the Center for Drug Evaluation and
14 Research.
15 And just for a little bit of history, the
16 Drug Shortage Program began in 1999. Its mission is to
17 address potential and actual drug shortages. We
18 currently have four full-time staff and a coordinator.
19 I'm the coordinator, and we try and facilitate
20 prevention and resolution of shortages by collaborating
21 with FDA experts, industry, and external stakeholders.
22 And really, you'll see as I walk through it -- and I'll

1 give some examples -- a lot of what we're doing really
2 is facilitation.
3 We also strive to provide drug shortage
4 information to the public. There are certain
5 situations where simply just having information is
6 really critical to allow folks to plan and understand
7 what's going on. We also strive to maintain outreach
8 with healthcare professional organizations, patient
9 groups, and other stakeholders.
10 We have very limited authorities that are
11 directly related to drug shortages. One specific
12 authority we do have is we have a notification
13 requirement for discontinuation of life-supporting and
14 life-sustaining therapies or therapies used for
15 treating debilitating diseases in the setting where the
16 product is one that's made by a sole-source
17 manufacturer. And in that setting, we require six
18 months' notification.
19 But really with regards to our authority,
20 manufacturing capacity is not something that we
21 control. We can't dictate the quantity of a particular
22 drug that being produced.

1 The Drug Shortage Program really is a program
2 that's been really built on the voluntary participation
3 of industry and other stakeholders out there in the
4 field that are willing to provide us with information
5 so that we can inform and react to what's going on in
6 the world of drug manufacturing.
7 And I provide this slide really just for the
8 purpose of reference. It provides the citation with
9 regards to discontinuation of a lifesaving product, and
10 there's a B part to this that I haven't include that
11 talks about circumstances where there are mitigating
12 circumstances where folks don't have to give six
13 months' notification. And then the next section which
14 talks about informing about drug discontinuation, and
15 we do that through our Drug Shortage Web site, where we
16 list product that are going to be discontinued.
17 And Doug showed you this slide too -- and I
18 think folks have probably seen it in other venues too -
19 - and that is this is what we have seen with shortages
20 over the last several years, and clearly an increase in
21 the number of shortages. And notable too is the number
22 of shortages that we've seen with sterile injectable

1 drugs. We don't have the numbers yet for 2011, but
2 from what we're seeing so far we expect that the
3 numbers will be higher. Sterile injectable products
4 will continue to be an important cause of drug
5 shortages.
6 And if we look at the different categories
7 that we have for reasons that drug shortages are
8 occurring. This is data from 2010, and we see that 54
9 percent are due to product quality or GMP issues; 21
10 percent due to delays and capacity issues; 11 percent
11 due to discontinuation; 5 percent due to raw material
12 or API issues.
13 And for 2011 although we don't have the
14 number yet, we expect that the data for the percent due
15 to product quality issues will be higher than what we
16 saw in 2010. Some of the reasons for shortages of
17 older sterile injectable drugs if we try and step up
18 and look at the issue more broadly, well, it seems
19 there's really not enough manufacturing capacity. The
20 other issue that affects the field is the consolidation
21 or clustering within industry; see fewer firms making
22 these products.

1 The top seven firms make up a very large
2 percent of the overall market. They also serve as
3 contract manufacturers, and there's a lot of
4 interrelatedness production going on within the
5 industry, a lot of production that's in essence tied
6 together, if you will, from firms contracting out
7 manufacturing as well as acting as contract
8 manufacturers. There's a lack of redundancy within the
9 field. Oftentimes multiple products are made on the
10 existing manufacturing line, so a problem can influence
11 multiple products.
12 In many of the products too, there are
13 complex manufacturing processes. Certainly sterile
14 injectable products represent real challenges in the
15 area of manufacturing. And also too, the older sterile
16 injectable products are not so tremendously
17 economically attractive.
18 So our approach to shortage prevention and
19 mitigation. As we work through a shortage, we're
20 considering the medical necessity of the product. The
21 risk/benefit of the product is always some that we're
22 looking at as we try and understanding approaches and

1 ways to mitigate a drug shortage. And we really try
2 and do everything possible within our authority to
3 continue availability while minimizing risk to
4 patients. When there are manufacturing and quality
5 problems, we work with the firm to try and address the
6 issues.
7 Flexibility is something that we can employ
8 to address shortages to mitigate the particular
9 shortage event, but we have to mindful of the risk and
10 understand what the potential risk are of mitigation
11 approaches and to make sure that the benefit/risk ratio
12 is still positive.
13 I've included here the definition of medical
14 necessity just for reference: A medically necessary
15 drug product is a product that is used to treat or
16 prevent a serious disease or medical condition for
17 which there is no other alternative drug available in
18 adequate supply that is judged by medical staff to be
19 an adequate substitute.
20 And I've also provided a reference to our
21 drug shortage map that's available on the Web site,
22 where I sourced the definition from. Folks may find

1 that a helpful reference.
2 And then moving on as far as approaches to
3 preventing or mitigating drug shortages. One of the
4 things we can do is we can encourage firms to ramp up
5 production, and that may help to address the shortfall
6 and the settings of a shortage.
7 We do try and expedite issues related to drug
8 shortages. For example, if a new manufacturing line is
9 needed, a new API supplier is needed, we try and
10 expedite the review of those supplements in order to be
11 able to address the shortage in a timely fashion. And
12 then in rare cases we do temporarily import drugs from
13 sources outside the U.S., so these are unapproved
14 sources, but we do this in the setting of critical
15 public health need. And when we consider importation,
16 one of the things we do is we look carefully to
17 understand the inspectional history of the plant
18 whether it be inspections that FDA has done previously
19 if the facility makes other FDA-approved drugs or
20 inspections done by another regulatory authority such
21 as the EMA.
22 In 2010, we had propofol as a drug that was

1 temporarily imported. In 2011, there was temporary
2 importation of Foscarnet, Ethiodol, Thiotepa,
3 norepinephrine, Xeloda, levoleucovorin, leucovorin. And
4 one thing just to note in general about importation is
5 that it's something that we investigate the setting of
6 a critical public health need, but when we reach out,
7 there may not always be available suppliers who are
8 willing and/or able to provide drug to the U.S. In
9 some instances, the shortages are not just the U.S.
10 alone but may be a more global nature, so it's
11 something that works in certain select circumstances
12 but is fairly limited and temporary in nature.
13 Now to move on and talk some about prevented
14 shortages in the years 2010. In 2010, there were 38
15 shortages that were prevented due to early notification
16 from firms; 16 were prevented through regulatory
17 discretion; that is, the judgment on the risk of the
18 quality manufacturing issue was able to be mitigated
19 and was outweighed by the benefit of the drug; 13 were
20 prevented through expedited review, either having a new
21 manufacturing site come online, new suppliers, or
22 changes in specifications or other changes; 8 were

1 prevented through encourages other firms to ramp up
2 their production. And again, this is dependent upon
3 those firms being able to do so.
4 In 2011, we've seen increased reporting by
5 manufacturers of potential shortages. This helps us to
6 be able to respond. So far in 2011 -- and this is just
7 the data to date -- we've had 99 shortages that have
8 been prevented due to early notification; 84 were
9 prevented through expedited review, getting a new
10 manufacturing site, supplier, or a change in
11 specifications that allowed the shortage to be
12 prevented; and 12 were prevented through regulatory
13 discretion, where based upon an assessment of the
14 situation the benefits of making the drugs available
15 outweighed the risk, and there may have been other
16 mitigating circumstances in there too.
17 I thought it might be helpful just to sort of
18 take a step back and think about a hypothetical
19 prevented drug shortage. And this really is a
20 hypothetical situation. I'll just sort of walk through
21 it, and I'm hoping that folks will find this helpful
22 because it really gets to some of the mechanics of

1 working through a drug shortage and how we approach
2 things.
3 Firm A calls the Drug Shortage Program to
4 tell that they've identified glass shards in their
5 sterile injectable drug product. The manufacturer has
6 noted this and is holding the product at the
7 manufacturing facility. This firm has 60 percent of
8 the market share of this medically-necessary product
9 that's used for treatment of a serious disease.
10 So when the Drug Shortage folks hear about
11 this, the first thing we do is we call Firm B. We know
12 that they're also manufacturing this product, and they
13 have 40-percent market share based upon our review of
14 marketing data.
15 Firm B is interested in helping and will
16 increase their production by 20 percent. They'll try
17 and do this as quickly as possible. It's going to take
18 them two weeks to get there. The 20-percent increase
19 will be difficult for Firm B because their
20 manufacturing capacity is already really tightly
21 allocated. But despite this, Firm B really is truly
22 interested in trying to help out and try to do what

1 they can to try and decrease the impact of the
2 shortage.
3 We're able to do some calculations in the
4 Drug Shortage Program. And given the inventories,
5 current production levels, usage rates based on
6 historical usage information, the time until the
7 shortage will occur -- and that is when folks will be
8 able to get product out there, healthcare providers to
9 administer to patients -- we're estimating in about
10 three weeks. So that gives us an idea of the timeframe
11 that we're working under.
12 So Manufacturer A does some additional
13 scientific and analytic work and has shown that the
14 glass shards can be removed by filtering the product
15 prior to administration. They've also checked to make
16 sure that after the filtration step the integrity of
17 the product is okay. They send this information, the
18 scientific data that they have, into FDA for FDA's
19 review.
20 FDA is able to expedite the review of the
21 data given the critical need for the product and the
22 potential shortage situation that we're seeing, and

1 we're able to allow release of the product under
2 enforcement discretion of the effective lots that have
3 the glass shards with a filter in place in order to be
4 able to filter out the glass shards. Also included
5 with this is a "Dear Healthcare Professional" letter to
6 inform folks about the necessity of filtering the
7 product prior to administration.
8 And with Manufacturer A's affected inventory
9 being able to be released with a filter, we are able to
10 avert the shortage of this medically-necessary product.
11 Critical here also is that Manufacturer A
12 also still has some additional work to do. They've
13 gone back to further investigate the cause of the glass
14 shards so they can get to the root cause of the problem
15 and can prevent this problem from happening during
16 their next production supply in order to avert
17 shortages in the future due to this particular reason.
18 So that's sort of the mechanics of what's
19 going on with the shortage, working with the
20 manufacturer.
21 What's going on within FDA CDER? Well, you
22 can tell the Drug Shortage Program is getting notified,

1 and then we're bringing in experts from within the
2 Center for Drugs, within the review divisions, and the
3 Office of New Drugs that regulates the particular
4 therapeutic areas of the products that are involved.
5 If it's a generic product, we're working with
6 the Office of Generic Drugs. As you can tell, given
7 that this is a product quality issue, the Office of New
8 Drug Quality Assessment is critical.
9 If it were a biologic product, either a
10 therapeutic protein or monoclonal antibody, we would be
11 working very closely with our Office of Biotechnology
12 Products. We're always working closely with our Office
13 of Compliance on these issues and others.
14 So you can see there's a lot of coordination
15 and facilitation going on both outside the FDA, working
16 with industry folks, and then also within the FDA,
17 bringing our experts together and responding to drug
18 shortage issues.
19 Just a few observations or things to note,
20 and that is that FDA plays a key role in working with
21 manufacturers to facilitate responses to prevent or
22 mitigate a drug shortage. Largely what we're doing is

1 a secondary response to mitigate a problem that's
2 already happened. Manufacturers play a key role in
3 responding to shortages is that they make the products
4 that doctors and patients use. It's important to
5 consider the root cause of a shortage, and being able
6 to get at the root cause can allow for a shortage to be
7 presented and can get to the issue of primary
8 prevention.
9 It's also important to recognize that some
10 shortages can't be prevented. Some shortages involve
11 unforeseen, unanticipated problems such as
12 manufacturing line breakdown or other events that cause
13 an unavoidable shortage. Manufacturers in the setting
14 of a shortage might not be able to make up production
15 in order to be able to meet the shortfall in the
16 setting of a shortage. And again, it depends on how
17 many manufacturers are making a particular product and
18 what additional capacity they may or may not have in
19 order to be able to address the need to address the
20 shortfall.
21 We described the situation with a filter, but
22 there may be other scenarios where the risks are

1 significant with the product, and we may not be able to
2 mitigate the risk.
3 And then some example of recent quality of
4 manufacturing issues involving sterile injectable
5 drugs, and I'll walk through. And what you'll see here
6 is really a spectrum of the types of problems that can
7 be encountered, and you'll see the range of the
8 seriousness of the problems, if you will. We've seen
9 significant quality issues that have occurred that
10 include sterility problems including bacterial/mold
11 contamination, particles of foreign matter, glass,
12 metal, fibers in the vials.
13 We've also seen crystallization of the active
14 ingredient; a precipitate forming; there may be an
15 interaction with some of the materials such as the
16 stopper of a particular drug product; or newly
17 identified impurities or degradants.
18 And then some of the issues that are more
19 easily able to be addressed: Error in labels or
20 packaging, which can be addressed by either providing
21 supplemental information, a "Dear Healthcare Provider
22 Letter," or enforcement discretion; (inaudible) of

1 specification results that don't alter the benefit/risk
2 in an unfavorable manner.
3 Other unforeseen or unanticipated issues.
4 There may be manufacturing equipment breakdown. There
5 may be natural disasters or other events causing loss
6 of manufacturing and in some cases loss of inventory.
7 Some examples of this may be a fire at raw material or
8 finished product manufacturing site. The Japan
9 earthquake; there were several potential sources there.
10 We were able to avert those or facilitate preventing
11 those through working with manufacturers. And then the
12 Icelandic volcano; folks probably recall when that
13 eruption occurred. That impacted transportation and
14 had some impact on availability of supplies.
15 With regards to flexibility, we can and do
16 exercise flexibility when appropriate to try and
17 minimize impacts on drug shortages in order to be able
18 to get drugs to providers and patients.
19 We can allow the distribution of product with
20 filters or other strategies to try and mitigate
21 deviations. And also we can alert healthcare providers
22 to deviations in products that may be occurring. We

1 can allow release of medically-necessary products with
2 extra testing and third-party oversight. We can also
3 build an exemption for medically-necessary products
4 into enforcement action such as consent decrees. We've
5 already talked some too about how we've used temporary
6 importation in the past.
7 For industry's role, potential solutions.
8 Certainly, planning ahead by adding redundancies to
9 manufacturing and raw material supplies to prevent
10 shortages of medically-necessary drugs can help. A
11 commitment to quality and proactively identifying and
12 promptly correcting issues can also help in the
13 prevention of shortages. Really, the goal here is to
14 try and prevent the sudden lack of a lifesaving
15 medication for consumers, patients, and healthcare
16 providers.
17 And also, we do greatly appreciate the
18 notification of the Drug Shortage Program as soon as
19 folks become aware of an issue that could impact upon
20 supply. And I've already talked about the 38 shortages
21 prevented in 2010 and 99 in 2011, and that's largely
22 due to early notification and our ability to work with

1 manufacturers to try and find solutions to prevent
2 shortages from occurring.
3 The continuing role for CDER's Drug Shortage
4 Program. We will certainly continue to work with
5 manufacturers. We're committed to do what we can in
6 order to try and be able to prevent or mitigate
7 shortages. We encourage voluntary reporting of
8 possible supply interruptions or decreases in supply.
9 We also think it's important to continue to track drug
10 shortages. As you've seen from the slides that show
11 the number of shortages over time, it's very helpful
12 for us to monitor what's going on and then also to
13 understand some of the reasons that shortages are
14 occurring.
15 Another critical role is our outreach to
16 healthcare professionals, consumers, manufacturers.
17 Some shortages can be prevented, other cannot, and
18 certainly having information allows folks to plan and
19 react to what's going on with the supply of a drug. We
20 recognize the value of having this information, and we
21 do try and post it on our Web site so that folks are
22 aware.

1 And then with this, I'll close. Just so
2 folks have as a reference, the Drug Shortage Web site,
3 the Drug Shortage email account where we appreciate
4 receiving notification of shortages.
5 And also one last note, and that is that we
6 have a webinar on prescription drug shortages on
7 September 30 at 11 a.m. We welcome folks to join that,
8 and Web address about that is listed there. So with
9 that, I'll close, and thank you. And then we'll move
10 to our next speaker, Erin Fox.
11 Want to welcome Erin Fox to the podium from
12 the Drug Information Service at the University of Utah
13 Hospitals and Clinics, and she'll be talking to us
14 about her update on the status of drug shortages,
15 causes, and significant change. Welcome, Erin.
16 MS. FOX: Thank you very much. I'm honored
17 to be invited here to speak today on a topic that I've
18 spent virtually my whole professional career on, drug
19 shortages. And I've already killed the monitor there.
20 There we go.
21 So I do have a disclosure statement to make.
22 I currently direct the University of Utah's Drug

1 Information Service, and our service does receive a
2 portion of our funding for the drug shortage
3 information we provide from Novation.
4 So why is someone from the University of Utah
5 here talking to you today in Washington, D.C., about
6 the problem of drug shortages. Our Drug Information
7 Service has always had a very standard way of providing
8 information to our physicians and clinicians at our
9 hospitals about drug shortages, and we began a
10 partnership with Novation and ASHP about 10 years ago,
11 when shortages began to become a real problem.
12 We continued to provide drug shortages
13 information on a public Web site. It's
14 ashp.org/shortages. There is no sign-on required to go
15 to that Web site, and what we do is we provide
16 information there to help clinicians really manage a
17 drug shortage for their patient.
18 It's important to know that we receive
19 voluntary report of shortages. We do not receive any
20 advanced notice of any kind. And I want to make it
21 clear that the collaboration what we have together with
22 our service, FDA, and ASHP, Novation, together we make

1 a really great team, and we provide the very best
2 information that way.
3 Let me go into a little bit about how this
4 shortage process works on our end. Anyone can go to
5 the public Web site and report a shortage. What that
6 does is it generates an email to a variety of folks,
7 but one of those emails goes to our Drug Information
8 Service, and it's our responsibility and my amazing
9 team there to investigate whether or not it truly is a
10 shortage. Well, how do we do that? We directly
11 contact the manufacturers to try to figure out if
12 there's a shortage or not. Sometimes there's not a
13 shortage, but sometimes there is. So we're working
14 directly to figure out from the manufacturer not only
15 is there a shortage but the reason why and the expected
16 duration.
17 So then we share back the information, and we
18 make a determination as to whether or not this
19 information should go on the Web site. And really if
20 most products are available, we probably won't post
21 something to the Web site. But if it looks like there
22 is pretty severe impacts for patients and clinicians

1 possible, then we will go ahead and err on the side of
2 reporting that information to the Web site.
3 We provide daily updates to that Web site,
4 sometimes 100 updates a week, on all the shortages that
5 are listed. And one of the things that we provide
6 that's a little bit different than FDA's page is our
7 drug information does a lot of research, and when there
8 are potential alternatives that can be used, we provide
9 that referenced, evidence-based information for
10 clinicians to use all over the country. That way
11 people aren't trying to reinvent the wheel as people
12 are struggling to manage these shortages.
13 Here is the current picture, and I want to
14 just make clear why are my numbers different than FDA's
15 number. There are a couple of reasons for that. We
16 include all shortages, biologic products, many products
17 that aren't considered medically-necessary products. So
18 these are the total number of shortages that have been
19 reported.
20 So just to orient you, along the horizontal
21 are each year from 2001 forward to the current date.
22 This is current as of September 15, and you can see

1 that the current trend is one of increasing shortages.
2 We saw that from FDA's slide, and you can see that the
3 trend really started in 2007 ramping up. So far in
4 2011, we have virtually matched last year's total, and
5 we still have a quarter of the year left to go. So we
6 are certainly on a trend for another record-breaking
7 year.
8 One last mention about this. Each column
9 represents just the number of new shortages identified
10 during that year. Those columns do not include any
11 leftover shortages from the previous year that might
12 still be active. So, for example, we have 210
13 shortages right now, but our drug information center is
14 currently following about 260 shortages.
15 This slide is very similar to what FDA showed
16 us that most of these drugs are injectable drugs.
17 Because we have just a few more numbers, our number
18 right now is we're right about 60 percent are
19 injectable drug.
20 This pie chart -- I'm not going to go into
21 all the reasons for shortages. I think we heard quite
22 a bit about that. One thing I want to show you here is

1 that the main reason that our Drug Information Service
2 identifies the most frequent reason for a shortage is
3 unknown. Now I realize unknown is not actually a
4 reason, but often the manufacturers were simply unable
5 to identify a reason.
6 Now FDA knows the reasons, but even though we
7 have that really nice collaboration, they can't always
8 tell them me what the reason is. And so if I can't
9 figure it out from media report, FDA's Web site, or
10 directly from the manufacturer, on our Web site we have
11 to report unknown.
12 Some of the other reasons we've heard about
13 today, manufacturing problems, supply constraints, raw
14 material. But again, that 55 percent of unknown,
15 that's really key to me because it shows that we don't
16 really understand all of the reasons why shortages are
17 happening. There are probably a number of reasons
18 perhaps we don't know why things are happening, cost,
19 supply issues, hoarding, things that just aren't in
20 play here because we don't know.
21 So very quickly, we know we've had
22 consolidation in the market, and certainly we've seen

1 generic injectables go from maybe seven manufacturers
2 down to one or two. We know that we have a free market
3 in our country. No company is bound to continue making
4 any drug no matter how medically necessary it is. And
5 there are lots of things that businesses can decide to
6 do that make great business sense but may not always be
7 the best for the patients.
8 There are certainly things that happen along
9 the line of profitability, choosing to fix a factory
10 line or not, sometimes there are annual quotas.
11 Sometime factories even just need to close down once a
12 year for a routine cleaning and vacations, and if
13 that's unfortunately lines up with a time when they're
14 needed to ramp up production, maybe they're not able to
15 help.
16 Again, we've heard quite a bit about
17 manufacturing problems that can happen, and there are
18 quite a few things in that realm, and I'm not going to
19 go into the details because we just heard a great
20 presentation on that.
21 I get to speak on drug shortages quite a bit,
22 and one of the things that I'm always struck by is how

1 many people feel that drug shortages are FDA's fault.
2 So one of the things that I wanted to look at was,
3 well, what about these inspections? What about these
4 483 forms? What are those like? The Pink Sheet in
5 June of 2011 did a very nice summary of what the top
6 violations are in 483s. And I think these really
7 mirror what we just heard in the slides before mine;
8 things like quality control, standard operating
9 procedures not being followed, failure to investigate
10 discrepancies, lack of sound scientific control, and
11 issues related to manufacturing performance.
12 So if FDA with these inspections is really at
13 fault, we would probably expect to see the curves
14 mirroring each other, 483's going up at about the same
15 rate that shortages are going up. This graphic kind of
16 maps that together, but it wasn't what I expected to
17 see when I mapped them out. Again, we heard that FDA
18 is just one of many partners. I don't think we can lay
19 all the blame at FDA's feet.
20 One thing I wanted to mention are
21 manufacturer recalls and their role as a cause of drug
22 shortages. Recalls on there are challenging enough, but

1 they can also worsen or precipitate a shortage. I
2 think if you think back to how severe that cytarabine
3 shortage was in the fall of 2010 a big reason for that
4 was when a recall happened for the firm that was really
5 the only one supplying the drug at the time.
6 Recalls can also create an immediate
7 emergency, wiping out a whole hospital stock of a
8 specific drug, and we had that happened at our
9 University of Utah System when one minute we had lot of
10 fosphenytoin that's used to help treat patients with
11 seizures. We had plenty of it in all our ICUs, and
12 five minutes later as soon as we got a recall notice we
13 had zero. So recalls can create immediate emergencies.
14 So when you think about all these things
15 together, what it points to is that in our country we
16 have an incredibly fragile supply chain. We've had
17 consolidation, so that we have fewer suppliers.
18 Manufacturers, hospitals, all use just-in-time
19 inventories. What that means is there is less
20 resiliency even if there is a short-term glitch.
21 Hospitals often don't even order a product until a
22 prescriber decided that they wants to order that

1 product. They may not even have any on their shelf, so
2 if there's none to purchase, it's an immediate shortage
3 for that hospital.
4 We also have variable distribution methods in
5 our country. There are three large wholesalers that
6 most hospitals and clinics receive their drugs from:
7 AmerisourceBergen, McKesson, and Cardinal. And each
8 one actually has a different system for how they
9 deliver their products. So that variability in itself
10 can create some challenges, and it also contributes to
11 those very odd situations of one hospital having drug
12 and the hospital across the street not having drug.
13 We've heard from manufacturers that it is
14 very difficult to increase and ramp up production to
15 make up 20-percent market share, and we also know that
16 global outsourcing of raw material can also be
17 problematic.
18 And one of the things I want to mention is a
19 new study that was published out of Ohio State on
20 offshore manufacturing problems. And these researchers
21 found that products manufactured in an offshore factory
22 had a much higher quality risk than those manufactured

1 in the United States. And the key reason for that was
2 the transfer of knowledge to a different culture with
3 different language and values.
4 So what is the trend for 2010-2011? Why are
5 things so bad right now? Well, a key trend for the
6 past two years has been one of extreme clinical impact.
7 We've had drug shortages for 10 years, but in the past
8 two years, we've really seen drug shortages where there
9 is no simple alternative. There may not be an optimal
10 alternative, and these shortages are requiring
11 treatment delays. We're talking about drugs like
12 antineoplastics used to treat cancer. These drugs are
13 settings in very specific regimens to be given at very
14 specific time. We don't have the outcome data to show
15 what happens when there are treatment delays. When a
16 drug in a regimen is no longer available, physicians
17 can no longer use an evidence-based regimen to treat
18 their patients.
19 We've seen shortages of antimicrobials, and
20 often these are the very last line therapies that are
21 short. These are therapies like Amikacin and
22 sulfamethoxazole/trimethoprim used to treat often

1 resistant infection, and once you need one of those
2 drugs, you're at the end of the line.
3 And electrolytes, it may sound simple to
4 substitute one calcium salt for another, but it makes a
5 very big difference for premature infants who really
6 need to receive calcium gluconate rather than a calcium
7 chloride. And there are series dosing errors
8 happening, and there are serious adverse effects
9 happening.
10 I wanted to look at the different shortages
11 by drug class just over the past two years. The light
12 blue represents 2010, and the darker blue is 2011
13 through September 15 of this year. You can see that
14 already this year we have matched or surpassed the
15 previous year's total for some drug classes.
16 And I'm specifically looking to central
17 nervous system drugs, and these are medications that
18 severely impact our emergency rooms, our operating
19 rooms, and really hospitals all over, medications,
20 seizure medications. These are critical, and we have
21 already surpassed those numbers from last year.
22 I've talked about antibiotics. I talked

1 about chemotherapy, so it's a wide variety of classes
2 of drugs that are being impacted.
3 There has been quite a bit of attention about
4 cancer chemotherapy drugs shortages, and I just want to
5 highlight what has the trend been for the past 10
6 years.
7 Well, I think you can see that we have had a
8 few chemotherapy shortages just about every year for
9 the past 10 years, but the big difference came in 2010,
10 when we jumped from 4 chemotherapy shortages in 2009 to
11 24 chemotherapy shortages in 2010. That's a huge jump.
12 Oncologists simply have not been impacted by shortages
13 over the past 10 years. This is a very new problem in
14 that area.
15 Now why did that happen? Again, there are a
16 number of reasons. But if we think about Teva having
17 to close their Irvine facility in the spring of 2010,
18 about a third of the drugs that were impacted by the
19 closure were chemotherapy drugs.
20 So what is the current status? In 2010
21 continuing into 2011, we've had manufacturing
22 difficulties at companies all at the same time. What

1 that's done is it has extended the shortage problem
2 even to plants with good supply. So even a plant has
3 no production issues, they may be experiencing drug
4 shortages simply due to the increase demands on their
5 production because of the other plants that can't
6 supply.
7 What this mean is we've had prolonged and
8 continued problems with very real patient impact. And
9 I think that we really do need action and solutions,
10 and there's no one solution that can fix this problem.
11 It's too complex. Solutions need to come from all
12 areas of the supply chain. There are certainly
13 regulatory solutions. Manufacturing can ensure that
14 people aren't hoarding drug and that drug is not being
15 diverted to the gray market. Purchasers can consider
16 including what are manufacturers doing to prevent drug
17 shortages in their RFIs when they go out to contract.
18 So those are just a few things that can be
19 thought about. I know that there are multiple
20 solutions to his problem. Thank you.
21 DR. COX: Thank you, Erin. Now I'd to invite
22 Roslyne Schulman and Burgunda Sweet to the podium to

1 talk about impact of drug shortages on hospitals and
2 health systems. Roslyne is the Director of Policy
3 Development for the American Hospital Association, and
4 Burgunda is in the University Michigan Health System
5 pharmacy, and I believe she's also representing the
6 American Society of Health-System Pharmacists. So,
7 welcome. Come join us.
8 MS. SCHULMAN: Thank you, and good morning.
9 Today, I and my colleague Dr. Gundy Sweet, the Director
10 of Drug Information Services at the University of
11 Michigan Health System will jointly present the results
12 of two independent national surveys that reviewed the
13 impact of drug shortages on hospitals and health
14 systems.
15 First to take care of some important
16 business, I'd like to state that neither Dr. Sweet nor
17 I have any conflicts of interest with regard to any
18 financial arrangements, affiliations, or other interest
19 with regard to the topic we're discussing today.
20 A bit of background about the two surveys.
21 With drug shortages becoming increasingly frequent, the
22 American Society of Health-System Pharmacists and the

1 American Hospital Association separately conducted
2 surveys of our members about six months apart. The
3 ASHP and the University of Michigan partnered on their
4 study. The purpose was three-fold: First, to quantify
5 the personnel resources required to manage drug
6 shortages; second, to define the extent to which recent
7 drug shortages have impacted health systems nationwide;
8 and third, to assess the adequacy of information
9 resources available to manage shortages.
10 The ASHP survey was sent to over 1,300 of
11 their members who are the directors of pharmacy at
12 hospitals and health systems. The survey was launched
13 in late October of 2010 and closed mid-November, and
14 the 353 respondents who completed the survey were
15 broadly representative of types of hospitals, bedside
16 staffing, geographic region.
17 Similarly, in June of this year, the AHA sent
18 a survey to hospitals using a rapid-response survey
19 methodology. The purpose was to find out how the
20 shortages have impacted hospitals including patient
21 care impact, hospital financial impact, and the ways in
22 which the hospitals are coping with drug shortages. The

1 survey request was sent to all community hospitals CEOs
2 on June 1 via fax and email, and data was collected
3 through mid-June.
4 The AHA received responses from 820 hospitals
5 and health systems, and again, respondents were broadly
6 representative of the universe of community hospitals
7 across all geographic regions.
8 In a nutshell, what the AHA and the ASHP
9 surveys founds was both strikingly similar and
10 troubling. Both surveys found that nearly all
11 hospitals, over 99 percent, reported experiencing one
12 or more drug shortages. These shortages happened
13 across all treatment categories.
14 In terms of the number of shortages, in the
15 first six months of 2011 nearly half of hospitals
16 responding to the AHA survey reported experiencing 21
17 or more drug shortages. The ASHP survey also found
18 that the number of shortages experienced increases with
19 the size of the hospital.
20 Both surveys also found that patient care
21 suffers as a result of drug shortages. Findings
22 include that patient care is delayed, that hospitals

1 must resort to treating patients with less effective
2 alternative drug, and that there have been adverse
3 patient outcomes as a result of drug shortages.
4 To delve into our results in a bit more of a
5 granular way, on this slide you see the data from the
6 AHA survey showing the number of unique drug shortages
7 that hospitals reported experiencing in the first six
8 months of 2011. And you can see well more than half,
9 57 percent, of hospitals reported more than 15
10 shortages in the 6-month period. The ASHP survey
11 report similar number of shortages in 2010.
12 This slide is from the ASHP-University of
13 Michigan study and demonstrates that the numbers of
14 drug shortages experienced by hospitals increases by
15 the size of the hospital in terms of the number of bed.
16 So the largest hospitals, those with more than 400
17 beds, nearly half experienced an excess of 30 unique
18 drug shortages in the 6-month period.
19 We can speculate on how the abundant numbers
20 of shortages may have impacted patient care and
21 research at the nation's foremost academic medical
22 centers. In fact at a House Energy and Commerce

1 Subcommittee hearing just this past Friday a cancer
2 researcher noted that enrollment of patients in some
3 clinical trials has had to be halted or delayed due to
4 drug shortages.
5 But even the smallest hospitals, those with
6 under 100 beds, had to deal with multiple drug
7 shortages. We see on this slide that 38 percent of
8 these experienced more than 20 drug shortages. Many of
9 these smaller facilities are located in rural areas,
10 some quite remote, and are crucial to providing access
11 to care. Clearly, shortages impact even the most
12 vulnerable patient population.
13 The AHA survey also took a look at how
14 frequently hospitals were encountering drug shortages.
15 What we found was startling. Nearly half of hospitals,
16 47 percent, reported that they experienced a drug
17 shortage on a daily basis. Another 40 percent reported
18 experiencing drug shortages on a weekly basis, and 13
19 percent reported it on a monthly basis. Only 1 percent
20 of hospitals claimed that they did not experience any
21 drug shortages in the preceding 6 months.
22 With drug shortages occurring so frequently,

1 it's not surprising that hospitals also report
2 significant time and resources dedicated to managing
3 shortages and significant patient impact. We'll
4 discuss these with you shortly.
5 I'm sure all of you have heard through the
6 media reports about the worsening shortage of cancer
7 drugs, which is certainly a significant matter of
8 concern. However, as you can see on this slide, and
9 consistent with what you heard from Dr. Fox earlier,
10 the AHA survey shows that drug shortages are occurring
11 across all treatment categories: Surgery, emergency
12 care, cardiovascular, GI, pain drugs, etcetera.
13 Further results from the ASHP survey indicate
14 that none of these shortages shows any geographic
15 preference; that is, shortages are being seen
16 nationwide with no drug shortage being more prevalent
17 in any given geographic area.
18 The AHA survey also asked hospitals about the
19 impact that drugs shortages have on their ability to
20 provide patient care on a day-to-day basis. What we
21 found was while hospitals are usually able to provide
22 timely and appropriate patient care by managing

1 shortages some hospitals report significant negative
2 patient impact. We believe that any negative patient
3 impact on patient care is unacceptable and should not
4 be tolerated. For instance, 20 percent of hospitals
5 report always or frequently having to delay patient
6 treatment; 11 percent report that patients received a
7 less effective drug; 11 percent also report that
8 patients did not receive the recommended treatment, and
9 3 percent of hospitals reported adverse patient outcome
10 as a result of the drug shortages.
11 The ASHP-University of Michigan study also
12 asked pharmacy directors about their global impressions
13 regarding shortages. What they found, as shown on this
14 slide, is that over half of hospitals report that
15 shortages are changing practice and compromising
16 patient care. Nearly all report that shortages are
17 increasing the burden. They all also report that
18 shortages have impacted their cost and are leading to
19 increased frustration directed to the pharmacy and its
20 staff.
21 MS. SWEET: Hospitals are taking many actions
22 to manage drug shortages with the goal of minimizing

1 the impact on patient care, and often multiple
2 strategies need to be taken into consideration and
3 implemented for any given drug shortage.
4 One of these techniques is close inventory
5 tracking and movement of stock throughout the
6 institution. While a seemingly simple task, this can
7 actually be quite time consuming. For example at the
8 University of Michigan, we have over 150 unit-based
9 dispensing cabinets; we use the Omincell brand. It's
10 not unusual for us to have a drug shortage that
11 actually touches a product that exists in most if not
12 all of those machines which requires us to adjust the
13 par level and physically manipulate the inventory in
14 all of those machines.
15 Institutions are also changing dispensing
16 practices, figuring out ways to deliver the same
17 medication but in a different way. Perhaps the best
18 example of this was the shortage that happened this
19 past year with the epinephrine 1 mg/10 mL syringes.
20 This is a critical care medication available in
21 emergency crash cart and on patient care unit
22 nationwide, used to treat life-threatening situations,

1 situations like anaphylaxis reaction.
2 When the syringes became unavailable, we had
3 to move them out of our Omnicell machines so that we
4 could preserve those syringes for our emergency drug
5 boxes that we provide to ambulances and for use in our
6 emergency room and crash carts. But this meant that
7 our Omnicell machine didn't have epinephrine. What we
8 had to do was create essentially pharmacy-made kits so
9 that we could deliver the 1 mg/10 mL epinephrine for
10 point of care and the patient care unit. This was done
11 by providing a 1 mg/mL amp, a filter needle, a 10 cc
12 syringe of saline, and directions for how to compound
13 that solution.
14 Now compounding a 1 mg/10 mL from a 1 mg/mL
15 is not a difficult calculation to do. However, you
16 have to remember that this dose is being delivered in a
17 critical care, urgent situation, and we're providing
18 medication to clinicians in a form that they're not
19 used to seeing. This makes us vulnerable for
20 medication errors.
21 Another technique that's commonly used is
22 allocating supplies to those who are in the great

1 clinical need. The AHA survey showed that 78 percent
2 of institutions that were surveyed in the first 6
3 months of this year had to implement a strategy that
4 required allocation of therapy for the medications that
5 were short. This too is a very time-consuming task. In
6 order for us to be able to decide how we allocate
7 therapy, we need to first define who's using the drug
8 and what they're using it for. And from there, we work
9 with our clinicians to identify which patient
10 population actually have an alternative to consider and
11 who do we need to restrict the access to who may not
12 have a very therapeutic alternative.
13 All of these techniques require that backup
14 inventory be added to the supply, and this often
15 requires that we establish contracts with new suppliers
16 to secure those drugs. The end result is that
17 clinicians are managing multiple shortages using
18 multiple different strategies and involving multiple
19 different people, a very time-consuming, labor-
20 intensive process.
21 In order to be able to effectively design and
22 implement an action plan, clinicians need good,

1 accurate information. We see in this slide the
2 resources that are available to most of us to be able
3 to access that information, and they includes sites
4 such as the ASHP drug shortages Web site and the FDA
5 drug shortages Web site but also communications from
6 group-purchasing organizations, wholesalers, or direct
7 communications with manufacturers. The percent use
8 reports the number of times in our survey that the
9 respondents noted that they went to those places for
10 information. And the high numbers illustrate that
11 clinicians are going anywhere they can to get
12 information about a shortage.
13 Yet despite the availability of all of these
14 different resources, 70 percent of respondents felt the
15 information available to them was not adequate. The
16 deficiencies really stem from the fact the information
17 is not available to those who were maintaining these
18 sites, and if they don't have the information available
19 to them, as Erin shared with us, it was at 55 percent
20 of the time the cause of the shortage is unknown; if
21 she doesn't have the information available to her, she
22 can't pass on to us across the country.

1 For example, 3 of the 4 hospitals report that
2 they rarely or never receive advanced notice of drug
3 shortages. It's not unusual for us to receive
4 notification of a shortage with only a 2-week supply of
5 drug on hand. Such short notice significantly reduces
6 our ability to allocate resources to those who are in
7 the greatest clinical need. There simply isn't enough
8 time or drug on hand to be able to do so effectively.
9 For this reason, advanced, timely notifications of
10 clinicians could make a big impact on patient care for
11 many products although admittedly not for all products.
12 As Erin mentioned, the cause of the shortage
13 is often not know. And while one could argue that the
14 cause is really not relevant, knowing this information
15 and being able to provide this information to those who
16 are most affected, the prescribers and patients, can go
17 a long way to help preserve the relationships between
18 healthcare providers.
19 Another piece of information that's often
20 missing is the expected duration of the shortage, or if
21 it's provided, it's provided with soft end dates that
22 often come and go. If I know that I have 100 vials of

1 drug available to me and that product needs to last for
2 three months, I can develop an action plan to restrict
3 that drug and make sure it last me. But if that 3-
4 month period comes and there's no product released, I'm
5 now in the difficult situation of having no drug on
6 hand and having to once again develop a new action
7 plan. This time one that's more challenging. This
8 puts tremendous burden on clinicians, and it also
9 destroys our trust in the product supply chain.
10 As you can imagine, development and
11 implementation of an action plan that minimizes the
12 impact on patient care is a very labor-intensive
13 process. The focus of the University of Michigan/ASHP
14 study was to quantify the personnel cost associated
15 with managing drug shortages.
16 We found that the expenditures associated
17 with these labor resources when applied to health
18 systems nationwide amounted to over $216 million a
19 year. I actually think this number understates the
20 amount that is being spent. And keep in mind, this
21 number does not include of the labor resources that are
22 factored in nonhospital institutions like home care

1 companies or in the outpatient world.
2 While the majority of hours are being spent
3 by pharmacists and pharmacy technicians, the process
4 truly is a multidisciplinary process, one that involves
5 physicians, nurses, and other who are involved in our
6 program supply chain.
7 It's important to note that most institutions
8 are managing this workload with existing staff. Few
9 respondents in our survey reported adding incremental
10 step to manage the workload. The end result is that
11 clinicians are spending more time finding product than
12 they are in being able to deliver clinical care to
13 patients.
14 The drug costs of shortages are not limited
15 to the labor resources though. The AHA survey and
16 other surveys that had been done over the course of
17 last year have shown that there are significant
18 increases in commodity cost as well, making the
19 cumulative expenditures considerable.
20 So in summary, there are numerous negative
21 impacts that are resulting from drug shortages. Those
22 include impacts on patient care, personnel resources

1 utilization, financial burden, and strained healthcare
2 professional relationships. The AHA survey showed that
3 two-thirds hospitals are reporting strained
4 relationship between pharmacy and medical staff, and
5 our survey showed very similar result, actually higher
6 numbers.
7 I'd like to end with closing quotes from our
8 survey which I thought was quite telling. One
9 individual notes "We spend more hours now putting out
10 these fires and finding medications than we do
11 improving patient care." And another note that in 30
12 years of practice he'd never seen problems like we've
13 having now. Thank you.
14 DR. COX: Okay. Thank you, Roslyne and Gundy
15 for fine presentation. And now what I'd like to do --
16 we're doing fine one time. We've got a few minutes,
17 and I'd like to open it up to the panel in case there
18 are questions of this morning's presentation before we
19 go to break. Just look around -- if there's any
20 questions that folks would like to ask, just raise your
21 hand.
22 MR. DECHRISTOFORO: I have a question.

1 DR. COX: Sure. And one thing we need to do
2 too since we this meeting being recorded if folks can
3 state their name before the speak that'll be very
4 helpful to our transcriptionist. Thank you.
5 MR. DECHRISTOFORO: My name is Bob
6 DeChristoforo, and I'm from the NIH in Bethesda,
7 Maryland, down the street. I have a question. It
8 sounded like when shortages are reported to the
9 University of Utah it's researched and it's also
10 information is passed onto the FDA. The other day I
11 reported something to the FDA on a shortage that wasn't
12 on the list. Is that information researched and maybe
13 sent back also? Is it a two-way street?
14 CAPT JENSEN: I can answer that. This is Val
15 Jensen from the CDER Drug Shortage Program at FDA, and
16 so, yes, we do pass information back and forth. If
17 there's a shortage reported to FDA and it's not on the
18 ASHP site yet and University of Utah may not know about
19 it as well, we let them know. We let both University
20 of Utah and ASHP know.
21 MR. DECHRISTOFORO: Thank you.
22 DR. COX: Any other questions for the panel?

1 Dr. Kweder.
2 DR. KWEDER: I want to ask the folks from --
3 the non-FDA speakers what experience is with what is
4 often called the gray market.
5 MR. DECHRISTOFORO: I can tell you also. The
6 gray market you don't know -- we avoid buying on the
7 gray market. But there were some vials of electrolytes
8 that were a hundred times the cost of what we were
9 paying in the past, and we really don't know where they
10 come from, and so we generally avoid the gray market.
11 DR. KWEDER: So say a little bit about what
12 -- I know what I mean by the gray market. I
13 mean by nontraditional sources of these drugs not
14 through your usual chain. How do you, just for the
15 audience and other on the panel who may not be familiar
16 with what it is, how do you find out about these
17 sources? You've already said what your experience is:
18 They usually are quite costly. Erin, do you want to
19 take?
20 MS. FOX: Sure. At our University of Utah
21 Health System, we often receive faxes, phone calls,
22 emails telling us that some small supplier has products

1 available.
2 Now we feel like there are very significant
3 safety issues with these products. We don't know where
4 they've come from. We don't know if they've stored
5 properly, so it's been our hospital's policy not to
6 purchase from these companies, and we have not ever
7 purchased from those companies.
8 But it is disturbing once you know that
9 people are out there saying that they have products.
10 And from time to time, I've actually called one of
11 those distributors and simply asked them, "Well, I
12 can't get any from the manufacturer. How did you get
13 some?" And they often can't tell me, and so often
14 they'll go, "Well, how much do you have?" And 9 times
15 out of the 10, they say that they just have a few
16 vials, three or four vials, maybe 10 vials. So really
17 that's not even enough to help for one day at our
18 hospital and sometime it's only enough for one patient.
19 DR. COX: Thank you. Yes. Could you state
20 your --
21 MR. COHEN: Just a follow-up on -- in this
22 on? I can't --

1 DR. COX: You're on, but please just state
2 your name for the record.
3 MR. COHEN: Okay. In addition to what we've
4 just heard, there are many other issues obviously, and
5 the whole idea of not knowing where they come from is
6 certainly a big one.
7 I'm very concerned about this particular
8 aspect. Really, there are situations where -- these
9 folks are professionals at following up after they --
10 they actually monitor wholesalers; they monitor the use
11 of these drugs, and at the earliest notification that
12 there might be a shortage, they may actually be
13 contributing to the shortage by purchasing all they
14 can.
15 We also know there are other secondary
16 wholesalers, gray market vendors, that although they're
17 legal they sometime wait until they get a call. They
18 don't even actually have any of the drugs that they're
19 marketing or soliciting. They're sending solicitations
20 to the pharmacies too, and they'll actually wait until
21 they get some calls and then follow up, and they have
22 professionals out there that will locate it. They will

1 set people up in hospitals, community pharmacies, other
2 practice facilities to actually purchase these from
3 them. And that worries me too. Again, you don't know
4 how they're stored, etcetera, etcetera. It just seems
5 like this should be a major topic to be investigated.
6 I know that FDA has been -- just recently I
7 saw some publications in the Federal Register -- a
8 publication in the Federal Register about going back
9 and looking again at requiring a pedigree but starting
10 at the point of the last authorized distributor of
11 record. Well, that's fine, but let's -- hopefully, we
12 can get that going soon, so at least we can see where
13 these are coming from.
14 Sometime we've seen actually six and seven
15 touches of the drug, and that involves purchasing not
16 from authorized distributors but from the field
17 somewhere. So it is a major concern.
18 DR. COX: Thank you, Dr. Cohen, for your
19 comment. Are there questions or comments?
20 DR. LICHTENFELD: Thanks, Dr. Cox. Len
21 Lichtenfeld, American Cancer Society. Two questions.
22 Question number 1 I this is a fairly simple answer. I'm

1 assuming that the drugs we're talking about here today
2 are post-1935 and don't fall into the category of not
3 having FDA approval in the past?
4 DR. COX: So we're not limiting it just to
5 approved drugs. I don't think -- we see shortages of
6 unapproved drugs too, so they're part of the discussion
7 also.
8 DR. LICHTENFELD: Which --
9 DR. COX: If you'd like to focus on approved
10 drugs, that's fine too.
11 DR. LICHTENFELD: No, that's okay. I guess I
12 opened up a door I don't necessarily want to go
13 through. I'm concerned cancer drugs which for the most
14 part I think are approved drugs. But putting that on
15 the table raise another interesting wrinkle as we've
16 been seen in the past with some other situations I
17 don't won't get into at the present time.
18 One things that has not been addressed here
19 among the possible shortages -- I don't know if any of
20 the panelist or the experts have had any experience.
21 Recently, I've seen some information in the literature
22 talking about the impacts of payment policies,

1 specifically Medicare payment policies as potentially
2 helping to lead to the shortages because of the
3 inability of manufacturers to increase prices in some -
4 - let's hope in a reasonable increase in a timely
5 fashion to meet the supply/demand issue. Do you have
6 any comments on that? Have you heard that from any of
7 the manufacturers?
8 DR. COX: There may be others that are better
9 able to address the issues with regards to payment and
10 the effect of payment. I don't -- other on the panel -
11 - this may be something we hear about over the course
12 of the day too, so let's log your question, and let's
13 come back to it, okay?
14 DR. LICHTENFELD: Thank you.
15 DR. COX: Okay. And then to Dr. Lisa
16 Bernstein, I was wondering do you want to make a
17 comment?
18 MS. BERNSTEIN: Not on that question, but I
19 have another question. Thank you. Ilisa Bernstein, in
20 CDER's Office of Compliance. I have a question for
21 Erin. In the updated presentation, there was a slide
22 with some bullets about some of the causes and the root

1 causes of some of these shortages, and you have an
2 amazing wealth of information, even more data than we
3 have.
4 And I'm wondering, you showed a little bit
5 about some of the problems alluded to consolidation in
6 the industry, and I'm wondering if you've actually --
7 you or others who have access to your data actually
8 done a dive into it and looked at some of the economic
9 drivers causing some of the shortage and some of the
10 other root causes based on your data?
11 MS. FOX: Right now we haven't done that, but
12 it is something that we're actively working on with a
13 group, and so we hope to have some more information
14 about that. Most of our efforts these days is simply
15 devoted to keeping up with the onslaught of drug
16 shortages and making sure that our hospital system is
17 taken care of and that we're providing the best
18 information we can for the nation.
19 DR. KWEDER: And I'll comment as well. Just
20 for the record, the work of FDA on this doesn't stop
21 here today. The whole Department of Health and Human
22 Services is involved in beginning to take a look at

1 what are some of the larger influences like payments,
2 financial incentives, other what I would put in the
3 category of systems problems that may underlies some of
4 this. My own assessment, with probably very little
5 knowledge, is this is not one thing, that there are
6 probably multiple contributors.
7 At FDA, we don't tend to focus on some of the
8 bigger economic issues that go into payments and that
9 sort of things. And the Office of Health Evaluation
10 and Planning in HHS along with other large agencies
11 will be working with us to try and we with them to try
12 and look at some of those. That's where a lot of that
13 expertise is.
14 DR. COX: Thank you, Sandy. So we're at 9:20
15 now, so we'll go ahead and --
16 MR. HOFFMAN: James Hoffman from St. Jude
17 Children's Research Hospital. I find it quite
18 impressive that FDA has prevented 99 shortages this
19 year. I wonder if someone from FDA could comment on
20 that great success. Has it been more communications
21 from the manufacturers? Has it been you just have more
22 experience and are able to do it better? Can you

1 comment further?
2 CAPT JENSEN: Yes. This is Val Jensen again.
3 Yes, you're right. It's been -- it's really a lot of
4 people in this room, a lot of industry representatives
5 that are in this room are responsible for that. They've
6 been letting us know, which is wonderful. We're glad to
7 see that. We've had more notifications this year than
8 ever before. We hope that continues, and that's really
9 what most of -- most of these prevented shortages are
10 due to companies letting us know when their either have
11 a quality problem that we can work through together or
12 they need expedited review on something to prevent a
13 shortage because of some event or they need to increase
14 production for some reason, and we're able to help with
15 out. Thank you.
16 MR. SCHMUFF: Yes. I would just like to say
17 that the Drug Shortage Program in my experience -- this
18 is Norman Schmuff from LNDQA -- has been very proactive
19 in preparing for these drug shortage meetings. We're
20 in nearly daily contact both the Office of Generic
21 Drugs and Office of New Drugs Quality Assessment with
22 the Drug Shortage Program. And by the time we have a

1 meeting with the Drug Shortage Program, they already
2 know what the burn rate is, what the usage rate is,
3 what inventories are. Frequently, they've already
4 identified alternative sources.
5 So I would say it's been one of the factors
6 has certainly been the very proactive approach that the
7 Drug Shortage Program at FDA has taken.
8 DR. COX: Thanks, Norman. So at this point,
9 we'll take our break, and we'll start back at 9:40. So
10 we have a little less than 20 minutes, so we'll see
11 back at 9:40. Thank you.
12 (Off the record)
13 (On the record)
14 DR. COX: We're at a little after 9:40, so if
15 folks could start to move toward their seats, and we'll
16 get going again here in just a minute. Thank you.
17 If folks can get back to their seats, we'll
18 get going again here in just a minute. I'm sure some
19 folks will still be filtering back in.
20 I thought we'd start out -- there was a
21 question asked about payment, and want to turn to Nancy
22 Davenport-Ennis who I think will provide us with some

1 additional comments/thoughts on the issue of payment
2 and its impact on the shortage situation. Nancy.
3 MS. DAVENPORT-ENNIS: (off mic) I'd like to
4 comment the fact that (inaudible) all of us as we get
5 ready to enroll (inaudible) (on mic) I would say our
6 experience with 27 percent of our patient population
7 last year almost 83,000 patients and additional 4
8 million others who called for some form of help, all of
9 them with access healthcare issues that with 25 percent
10 of the population being Medicare, 16 percent of the
11 population being Medicaid what we see is if the
12 manufacturer cannot have some degree of a margin on the
13 medication they simply do not stay in the market; it's
14 not going to be made available, particularly within
15 that sector.
16 And so I think as the FDA is struggling to
17 deal with this issue the ask that we have of the FDA is
18 to stay the course and continue to work with other
19 government agencies who may be very helpful in trying
20 to resolve these matter because some of the matters
21 will have to be resolved by agencies other than the
22 FDA. So we're here to lend our support to that and to

1 thanks the American Cancer Society for calling that
2 forward.
3 DR. COX: Thank you, Nancy. And now I'd like
4 to invite you to the podium to provide your
5 presentation on improving patient care with regulatory
6 and policy initiative. Nancy is from the National
7 Patient Advocacy Foundation, and she'll also be joined
8 by Diane Hamil and Abigale Hamil.
9 MS. DAVENPORT-ENNIS: Yes. I thank you for
10 the opportunity to present on behalf of the patients
11 that we serve through the Patient Advocate Foundation.
12 We think this topic is very relevant. Every patient
13 who comes to our organization is there because they've
14 had an access to healthcare issues. Every patient
15 who's facing an access to healthcare issue typically
16 assumes that if we can get reimbursement resolved or if
17 we can handle social service needs and underlying needs
18 of that family that indeed we can get them to the care
19 that they need.
20 For patients who are now confronting the
21 issue of drug shortages as part of their challenge to
22 getting to the protocol prescribed by their treating

1 physicians, it's a very difficult place in which they
2 find themselves.
3 Let me share with you that while we're here
4 today to answer primarily six questions posed to us for
5 today, for patients it's a broader list of questions.
6 And I'd like to share with you some of the questions
7 that the patients are asking.
8 Number 1: Why is there this shortage? Don't
9 they know there are people like me with cancer or with
10 any of the other 274 chronic diseases that we're
11 handling in America? They have real fear in the areas
12 of how long will the shortage last? What is it going
13 to mean to me if I have to step out of protocol and go
14 to an alternative drug? Will the management of disease
15 be impeded? Will I have side effects that are going to
16 be far more serious than those that I'm currently
17 having? And perhaps I'm not having side effects with
18 the drug that I have.
19 Patients are very involved today in
20 understanding the financial implication of their
21 treatment intervention. And when they're moved from
22 one drug to another, the alternative drug, that drug

1 may or may not be on their formulary. That drug may or
2 may not be covered. That drug may or may not be on the
3 same tier for their copayment or co-insurance
4 participation as the one that they're on. These are
5 very real questions. They're very real concerns.
6 Patients who are dealing with this are not
7 only now dealing with disease they have now heightened
8 anxiety and real fear not only about the disease and
9 the outcome of that but also what is going to happen to
10 me during this interim period of time. And I think
11 there is not a single person in this room or America
12 that cannot deal with that fear.
13 We've heard many comments today in terms of
14 what's driving the shortages. We agree with the
15 comments that have been presented and will work
16 diligently in the country with each of you to try to
17 find a solution. We think that the FDA indeed is to be
18 commended for having this hearing today and for
19 inviting stakeholders to come in to work with you
20 across many lines. But at the end of the day, the
21 thing I want to leave you with is not the fact that we
22 have over 700,000 closed cases documented by 260 fields

1 of data that we collect for each or that we serve on
2 average about 4.5 million patients either through case
3 management or information because every single one of
4 those numbers represents a human being diagnosed with a
5 chronic debilitating and/or life-threatening condition.
6 Every single one of those human beings has a family,
7 and they have loved one, and they have friends who want
8 to see them get better.
9 The story that we need to tell today is best
10 told by Diane Hamlin, the mother of Abigale Hamlin who
11 is here with me today and dad, Ty Hamlin, who is in the
12 audience. This family has been dealing with the issue
13 of drug shortage, and they have traveled from the state
14 of Washington last night, arriving in the city after 11
15 o'clock, to be with you and to tell you their story of
16 drug shortage. So let me introduce to you Diane and
17 Abigale Hamlin.
18 MS. HAMLIN: Good morning. Thank you for
19 allowing me to -- for this opportunity to tell our
20 experience with the drug shortage. My name is Diane
21 Hamil. I'm the mother of Abigale Hamlin who at 16 was
22 diagnosed with acute myelogenous leukemia early this

1 year in March. The first chemotherapy round went very
2 well.
3 As we began the round 2, we were told there
4 was a shortage of one of the chemo drug that she
5 previous received, daunorubicin. They called many other
6 hospitals and were unsuccessful to receive the drug.
7 Abi would have to be given an alternative drug called
8 doxorubicin. We were told that it would still kill the
9 cancer cells, but it was not as kind to the body. We
10 didn't have any idea what this meant until three days
11 after her last treatment when her pain became so
12 unbearable she pleaded with the ED doctors to do
13 something about her throat. She was already taking
14 oxycodone, and yet her pain level was an 8.
15 The doctors told us the pain was from the
16 mucositis caused by the doxorubicin. She was in so much
17 continuous pain she was given Dilaudid via an IV
18 continuous drip at PCA so she could push a button every
19 4 minutes, and she got a bolus every 4 hours.
20 The doctor said Abi would not be pain free.
21 They could only make her as comfortable as possible.
22 The mucositis went from inside her mouth, throat,

1 stomach, and on. She could not eat food or even get her
2 nutrition through her nose NG tube. She had to be feed
3 intravenously straight into her blood. Now this became
4 another concern of a possible infection site.
5 During this time, she was given a suction
6 tube to use to suck up the mucus in her mouth. From the
7 minute the nurses gave her this, she never let go for
8 two weeks. It seemed like she held it and used it every
9 minute of the day. The three days we didn't sleep she
10 held it in her hand, close to her mouth as her eyes
11 closed until the myoclonic jerks, jerked her awake. The
12 myoclonic jerks occurred every minute to a minute and a
13 half for a few days until they found yet another drug
14 to give her to prevent the jerks, but at least she was
15 able to get some sleep.
16 During this time, she became anxious and had
17 several anxiety attacks. She developed OCD tendencies,
18 becoming obsessive with cleaning instead of sleeping.
19 She would climb on her bed and get to her knees to
20 reach as high she could to reach the best light in the
21 room, to look in a mirror so she could get all the
22 mucositis sucked out of her mouth. She stood on chairs

1 to clean and dust. There was no sleeping for anyone. My
2 daughter became rude and said very hurtful things to
3 people, and I hope she never remembers this. This was
4 not my daughter. I remember asking the doctor when
5 will my daughter be returning to me.
6 The psychologists were brought in to
7 evaluate; more drugs and antidepressant. She already
8 was taking so many drugs. I just wanted my daughter
9 back.
10 At the end of the second week, her bone
11 marrow began to recover. The mucositis was subsiding.
12 Abi was being weaned off of the pain medications. Days
13 later, she was experiencing withdrawals from the
14 narcotics that she was given for the pain. She was hot
15 one minute and freezing the next and sometimes at the
16 same time. She was unpleasant and rude to friends and
17 family. We were all experiencing the withdrawals.
18 Finally, day 26, we were leaving the hospital
19 for a break. We were so happy and joyous to be over
20 this round and leaving the horrible experience behind
21 us.
22 As we left, I saw 12-years-old Makayla

1 through the window of her hospital room with a suction
2 stick in her hand. She had been diagnosed with AML just
3 weeks after Abigale. My heart sank with sadness. I knew
4 exactly what she and her parent were going through.
5 There was plenty of discussion regarding the
6 chemotherapy drug shortages at the Ronald McDonald
7 House where we stayed. In the end, we know there is
8 nothing we can do but pray for our kids and hope we get
9 the drugs our children need to cure their cancers.
10 Having cancer is a horrible thing for anyone to go
11 through especially a child. The treatments are not
12 pleasant, and the possible side effects are horrible
13 and will be a lifetime concern to the taxing of her
14 organs.
15 If the drugs are out there that are kinder to
16 the body and we can get the children back on their feet
17 playing and back to school, we need to get them. Thank
18 you.
19 MS. HAMIL: Hi, everyone. I'm Abigale
20 Hamlin. Cancer is very scary. Personally, the scariest
21 part for me was how the drugs made me feel. I was
22 scared of the pain and how it didn't make me feel

1 right.
2 Like my mom said, it was a very dark time for
3 me. It was brutal. Not only did this affect me but the
4 other kids taking the same thing. If I was given the
5 right chemotherapy drug, I wouldn't have had to go back
6 into the hospital, the nurses won't have to give me so
7 much attention, my doctors wouldn't have to prescribe
8 me as many drugs, and we wouldn't have to go through
9 this mess.
10 (Applause)
11 DR. COX: Thank you, Ms. Hamil and Abigale
12 for sharing your experience. Now I'd like to invite
13 Davria Cohen to the podium to give her perspective.
14 MS. COHEN: Good morning, and thank you all
15 for allowing me to be here and share my story with you.
16 Okay. Soon as I figure out how to -- No, that didn't
17 do it. (Pause) Got it. Okay. I have no conflicts of
18 interest, but I'd like to say that my husband and I are
19 regional volunteers for the Oley Foundation for
20 Parenteral and Enteral Nutrition, which is a support
21 and education and also research organization.
22 Over 29 years ago I was involved in a car

1 accident. My seatbelt severed my mesenteric artery and
2 perforated my small and large bowel. Consequentially,
3 now that I only have about 90 percent of my bowel, I
4 suffer from significant malabsorption and chronic
5 diarrhea, and I'm at high risk for dehydration and
6 electrolyte imbalance. Although I do eat a specialized
7 short bowel syndrome diet, I cannot digest or absorb an
8 adequate amount of nutrients or fluids. I depend on
9 parenteral nutrition or TPN to survive.
10 I also want to tell you that following
11 surgery and chemotherapy I am five years in remission
12 from metastatic fallopian cancer, which was unrelated
13 to short bowel syndrome, and the only reason I'm
14 mentioning that today is that one of my chemo drug is
15 no longer available.
16 What is parenteral nutrition? Parenteral
17 nutrition involves feeding intravenously, bypassing the
18 usual process of eating and digestion. Customized,
19 sterile formulas are administered through a central IV
20 line such as a Broviac or a port using a special pump.
21 These formulas contain amino acids, dextrose,
22 electrolytes, lipids, trace elements, and added

1 vitamins. Meticulous care must be taken to avoid
2 infection, which can quickly spread throughout the
3 bloodstream. This is called a catheter-related
4 bloodstream infection, and this type of infection is a
5 serious risk for those on parenteral nutrition because
6 parenteral nutrition is very high in sugar.
7 To preserve the life of the catheter and to
8 decrease the risk of infection, it is important to
9 limit its use.
10 I want to tell you a little bit about what
11 parenteral nutrition has meant to me and still means to
12 me. My port, which I guard every time I'm in the
13 hospital I guard -- I beg nurse please, you know, use
14 alcohol, wipe off -- even if you're giving me a
15 piggyback infusion, you must -- it's going into my
16 heart, so you must be careful. Without parenteral
17 nutrition, I would've died in 1982 at age 32. Instead,
18 I just celebrated my 62nd birthday and my 41st
19 anniversary. Without TPN, I would not have been able
20 to raise my children who were then 7- and 2-years old.
21 I would not have been able to contribute to society and
22 to my family by working most of my adult life. I would

1 not have completed my college degree nor had the
2 occasionally opportunity to visit some historical and
3 beautiful locations. I would not have been able to
4 start the history group which I currently run. And I
5 would not have known the joy of singing in a choir that
6 entertains at nursing homes.
7 For years, I was on TPN and everything was
8 fine. I very rarely had any altercations done my
9 solution. Occasionally in the summertime potassium
10 would be increased, something minor. The first things
11 that happened was until about a year ago I added a
12 double vial of MVI, multivitamin for infusion, 12 to
13 each TPN bag. It contained 12 different essential
14 vitamins but not vitamin K. Due to clotting issues,
15 I'm supposed to minimize my intake of vitamin K. More
16 than a year ago, MVI-12 became unavailable; so MVI-13,
17 which does have vitamin K in it, was substituted.
18 However, since the amount of K in the MVI-13 is small,
19 it has not greatly affected my INR or clotting values.
20 But several years ago, no IV multivitamins
21 were available at all. And recently in some parts of
22 the country -- I remember somebody saying there is no

1 part of the country that's affected greater than
2 another, but for some reason, in some parts of the
3 country people could not obtain infusible
4 multivitamins.
5 This past May calcium gluconate became
6 unavailable. And so calcium chloride was substituted.
7 Since calcium chloride is less compatible with other
8 parenteral nutrition components, I was cautioned to
9 hold each bag up to the light before infusing to check
10 for crystals, but I was assured that since my tubing
11 contained a filter that if there were crystals I would
12 still be all right, but this is still not an optimal
13 situation.
14 In June I told that magnesium sulfate was
15 unavailable, and since magnesium chloride, which was
16 substituted for the magnesium sulfate is not compatible
17 with sodium phosphate, I require a separate IV bag that
18 contains nothing but sodium phosphate is infused over
19 three hours in addition to the regular nine hour
20 parenteral nutrition infusion. I was cautioned to
21 flush thoroughly with saline after finishing one bag
22 and before beginning to infuse the other.

1 So now instead of infusing one bag over nine
2 hours, I am infusing two bags over 12 hours, and this
3 change has diminished my quality of life. I no longer
4 want to go out in the evening; carrying the 250 ml bag
5 of sodium phosphate and the pump in a fanny pack is
6 somewhat awkward, and it's heavy, and I really don't
7 enjoy walking around with it.
8 But more importantly, this change increases
9 my risk of infection because my infection -- and by
10 infection I'm talking about infection to my catheter.
11 My infection risk goes up with each additional time I
12 use my IV line. Now I have the extra bag to infuse,
13 and after it's done, it must be flushed with two 10 cc
14 syringes of saline.
15 This drug shortage is scary. What essential
16 parenteral nutrition component will I be unable to
17 obtain next? Well, I know the answer to that because
18 after I turned in my slide I was in contact with my
19 nutrition support dietician, who by the way has the
20 undesirable job of having to recalculate my formula
21 every time something is scarce. On Wednesday, I spoke
22 with Nicole Beall (ph), my dietician; and she told me

1 that "As of your next TPN batch, we will be out of
2 multi-trace element 5 and will switch you to multi-
3 trace element 4, which does not have selenium. So
4 there will be no selenium in your TPN." Also, she
5 said, "We are in limited supply of sodium phosphorus
6 and potassium phosphorus." So that will be the next
7 thing after that to change. As I said before, I depend
8 on TPN to live. It is my means of nourishing myself.
9 Since I'm an Oley Foundation regional
10 volunteer, I contacted the foundation, and I contacted
11 other patients, TPN patients, and they very frightened.
12 Many of them cannot eat at all. I'm fortunate I can
13 eat a little bit, but I know I absorb very poorly
14 especially calcium. Calcium and vitamin D are things I
15 do not absorb well.
16 So I've gotten posting and letters. One --
17 actually, I saw her comments in the packet; her name is
18 Sarah Batalka, and her comments are included in your
19 packet. She said "I have a mitochondrial disease, and
20 I require large doses of IV magnesium sulfate daily in
21 addition to other electrolytes for survival. My
22 homecare company only has 10 weeks' worth left. There

1 is no substitute for the drug, and without it, I will
2 die."
3 People have told me about IV vitamins and
4 calcium as I have the problem with calcium gluconate,
5 and one woman said this is a life-threatening problem
6 for those who cannot eat, "It's not like any of us can
7 eat a salad or cheeseburger to sustain us."
8 Another problem for us is ethanol locks,
9 which many people use -- instill into their catheter to
10 prevent bloodstream infection. Commodine (ph) was
11 another, and as I've now found out, changes to trace
12 element.
13 Anyway, thank you very much, and I look
14 forward to hearing the rest of the presentations.
15 (Applause)
16 MS. COHEN:
17 DR. COX: Thank you, Davria for sharing your
18 experiences with us. Now, Jay Cuetara, I'd like to
19 invite you to the podium.
20 MR. CUETARA: Hello, my name is Jay Cuetara,
21 and I live in San Francisco and work for a Fortune 50
22 technology company. I'm currently 49-years old. I'd

1 like to begin by thanking the organizers of this FDA
2 workshop for the invitation to speak at today's
3 session. As you'll hear in my comments, this is a very
4 important issue for me personally as well as for the
5 thousands of others who have been and/or will be
6 affected.
7 In April of 2009, I was officially diagnosed
8 with stage 4 rectal cancer, which had already spread to
9 my lungs. Fortunately before the diagnosis, I had been
10 and luckily continue to be asymptomatic. For the most
11 part, I live a pretty normal life working full-time,
12 spending time with friends and families, vacationing,
13 and watching really bad reality TV. I'm able to
14 accomplish these things due to the wonderful care I'm
15 receiving from the incredible medical staff at UC-San
16 Francisco's Helen Diller Cancer Center.
17 Now in April of 2009 when I first met my
18 oncologist, Dr. Alan Venook, I could tell he knew
19 exactly what he was talking about. He made it very
20 clear to me that a cure was highly unlikely but that we
21 should be able to treat the rectal cancer as a chronic
22 condition, providing me with a good quality of life for

1 years to come.
2 Critical to treating the cancer would be the
3 targeted use of chemotherapy. Dr. Venook assured me
4 that most of the rectal cancer chemo cocktails had been
5 around for many years and were very effective with
6 minimal side effects. I soon began a 12-cycle regimen
7 of FOLFIRI, which concluded December of 2009.
8 Fourteen months later after a routine PET CT
9 scan this past February, we found that the cancer had
10 spread to my L5 and my T10 vertebrae. After two
11 CyberKnife radiation treatments, I started a 12-cycle
12 regimen of FOLFOX this past June.
13 Now on the day of my sixth cycle of FOLFOX,
14 just this past August 9, after having been given all of
15 premeds, I was informed that the 5-FU injectable drugs
16 was not in stock and I wouldn't be able to have chemo
17 that day. My first reaction, honestly, was just utter
18 surprised. I wasn't angry. I was just surprised like
19 "What, you know, what's going on here?" I had not
20 known that there could be issues with lack of chemo
21 drugs.
22 I asked to speak with the pharmacist, who

1 told me that UCSF had had supply issues with the 5-FU
2 injectable drugs specifically as well as other chemo
3 drugs used for breast, ovarian, and other cancers. She
4 told me that the chemo drug supply issue was so serious
5 that the UCSF infusion center has a pharmacist that
6 spends the bulk of his time sourcing drugs to ensure
7 availability. At that point, I was dumbfounded. The
8 question I then asked myself was how in the United
9 States of America could critical lifesaving or life-
10 prolonging drugs be in short supply.
11 I went home that afternoon and spent the rest
12 of the day researching the issue in order to better
13 understand the situation. I came across and read the
14 Drug Shortages Summit, November 5, 2010, Summary
15 Report. I contacted the American Society of Health-
16 System Pharmacists. I contact APP Pharma, Mylan
17 Pharmaceuticals, Teva Pharmaceutical, the manufacturers
18 of the 5-FU injectable to find out their reasons for
19 the inability to provide the drug. I also contacted
20 U.S. Senators Dianne Feinstein and Barbara Boxer along
21 with Congresswoman Nancy Pelosi, who is my
22 congresswoman. I concluded that afternoon by calling

1 U.S. Senator Amy Klobuchar's office to discuss the
2 legislation she's sponsoring to help resolve this
3 issue.
4 Now during this research I also learned that
5 160 plus of the drugs currently in short supply have
6 nothing to do with cancer treatment as we've heard
7 today and that the bulk are generic drugs whose
8 efficacy has been proven time and time again and that
9 in most cases the reason for the shortages were not
10 known. Once again, the question how in the United
11 States of America could this be happening came popping
12 into my head.
13 In addition to speaking about my own personal
14 cancer situation, I want to ensure that I also speak
15 for the thousands of noncancer patients who most likely
16 never knew or will never know that the most effective
17 drug that they should've been given was not available.
18 As I mentioned earlier, 160 plus of these
19 drugs on the shortage list have no connection to cancer
20 treatment and are typically given to patients in
21 emergency situations: Situations like surgical
22 patients not getting the best anesthesia drug;

1 premature babies not getting the best preservative-free
2 antibiotic; herpes patients at a loss for a drug that
3 will ease their situation; mental patients not getting
4 the best drug to help them think clearly and reduce
5 nervousness.
6 As I stated earlier, I'm not part of the
7 health profession, but I have learned a lot over the
8 last 30 months while dealing with my cancer. I also
9 have a lot of close friends who are anesthesiologists,
10 hospitalists, and nurses. I asked them how this
11 critical drug shortage affects them and their ability
12 to treat their patients. Regardless of health issue
13 and to a person they all said substantially. Whether
14 it's having to use a less effective drug, having to
15 deal with dosing issues and/or medication error, delays
16 in treatment, or the time they and their counterparts
17 have to spend dealing with these issues, it is greatly
18 impacting patient safety and increasing the cost of
19 care.
20 I find it incredibly ironic that the least
21 expensive drugs are the one we have the greatest
22 difficulty in sourcing. I am convinced that a detailed

1 cost/benefit analysis would clearly show that the
2 benefits, financial, societal, and emotional,
3 associated with ensuring the availability of these
4 critical drugs would far outstrip the cost. In other
5 words, sometimes you have to spend a little to save a
6 lot.
7 Now I am actually one of the fortunate cancer
8 patients. UCSF was able to acquire the 5-FU injectable
9 drug, and my chemo treatment was delayed by just one
10 week. I'm not back on a regular schedule at least for
11 now, and in fact I have my eighth cycle tomorrow when I
12 return to San Francisco.
13 But the medical professionals and the drug
14 experts in this room know that there are many
15 chemotherapy protocols where even a one-week delay
16 greatly impacts the efficacy of the treatment and could
17 potentially change what would normally be a cure to
18 life prolonging and life prolonging to imminent death.
19 Many in colleges have be put in the position
20 of rationing care, having to determine which of their
21 patients will receive a limited chemo drug and which
22 won't. Again, the question I ask myself: How in the

1 United States of America could this be happening?
2 Let me conclude with the following. I firmly
3 believe that this group of pharmacists, doctors,
4 medical professionals, pharmaceutical representatives,
5 and government officials are here today to ensure that
6 the thousands of people like me have access to the best
7 critical drug at the right time and every time it's
8 needed. Everyone in the room understands the root
9 causes of the critical drug shortages and everyone in
10 this room has a vested interested in solving the
11 problem. So let's get it done. Let's fix this problem
12 now. Thank you all very much for your time today.
13 (Applause)
14 DR. COX: Thank you, Jay. And now I'd like
15 to invite Barbara Bennicoff to the podium to share a
16 story from one her patient. Barbara.
17 MS. BENNICOFF: My name is Barbara Bennicoff.
18 I am a homecare nurse, and this is a statement written
19 by my patient who has mitochondrial disease and is
20 unable to be here today because she is bed-bounded.
21 "My name is Sarah Batalka, and I am a 30-
22 year- old women from Quakertown, Pennsylvania. I'd let

1 to share with you the devastating impact the drug
2 shortage in our country is having on me. In order to
3 do that, I first need to give you an idea of my medical
4 condition.
5 I was born with a mitochondrial disease,
6 which is a form of muscular dystrophy. In addition to
7 chronic pain, muscle fatigue, and the inability to
8 walk, this disease has also affected my organs and
9 systems. I had a fairly normal childhood with
10 relatively mild symptoms, but as the disease
11 progressed, I went from being very independent to being
12 almost totally dependent on the help of visiting
13 nurses, a team of doctors and specialists, a home
14 infusion pharmacy, medical equipment, many medications,
15 and my mother, who is my sole caregiver.
16 Today, I am home-bound and bed-bound. Both
17 my bed and power chair are surrounded by medical
18 equipment. I take numerous oral medications, and I
19 receive intravenous medications through a port that was
20 surgically implanted in my chest. Medical supplies and
21 injectable medications are needed to maintain a port.
22 One of the many mitochondrial disease effects

1 my body is that is my kidneys can't hold onto the
2 electrolytes such as magnesium and potassium that are
3 essential for survival. For six years now I've needed
4 help maintaining my blood levels of these and other
5 critical electrolytes. In addition to receiving them
6 in pill form, I get them through IVs that provide
7 enormous daily doses. I absorb very little of what is
8 taken orally, and it is nowhere near effective at
9 maintaining my blood levels. I must receive my
10 electrolytes in IV form. I cannot survive without
11 them.
12 In April of this year, I got the worst
13 possible news. I was told by my home infusion pharmacy
14 that their supply of IV magnesium sulfate, a key
15 ingredient in my IV bags and one without I cannot
16 survive, was dwindling and that they only had enough to
17 fill my IV bags for a few more week. To give you some
18 idea of the impact this news had one me, please
19 consider what it would feel like to you if someone told
20 you there would only be enough air supply left for you
21 for three weeks of breathing.
22 I so depend on this medication for survival

1 that its unavailability would indeed be the same as you
2 having your air supply cut off. I had been unaware of
3 the nationwide drug shortage crisis until I personally
4 affected. Because visible particulate matter was found
5 in what is supposed to be a sterile injectable bag, a
6 plant was shut down, and this I was told created a
7 nationwide shortage affecting individuals like myself
8 who depend on this life-sustaining drug. Even now,
9 manufacturers are just not able to keep up with the
10 increased demand.
11 Magnesium sulfate is needed by many different
12 kinds of patients with many different medical
13 conditions. For us, there is no substitute, just as
14 there is no substitute for oxygen and you can't survive
15 without it.
16 Because of halted and delayed production,
17 hospitals in my area are in short supply of IV mag
18 sulfate. If the product is unavailable and if there is
19 no equivalent substitute, there is simply no way to
20 treat patients who for whatever reason have low blood
21 magnesium level.
22 On a normal day even prior to this shortage,

1 hospitals tended to be uncomfortable with the amount of
2 electrolytes I require. They surely will not want to
3 use so much of a product that is now in such limited
4 supply to treat just one patient when it could
5 otherwise be used to treat several patients.
6 Fortunately in my case, my home infusion
7 pharmacy was at the last minute able to get enough IV
8 mag sulfate to treat me for a few months. Eventually
9 if the shortage isn't resolved and home infusion isn't
10 able to get more products, I will have to be admitted
11 to the hospital until home infusion can provide it for
12 me again. If the hospital does not have enough IV mag
13 for me, my blood level of magnesium will get too low. I
14 will suffer seizures, cardio events, and eventually
15 cardiac arrest. I will die.
16 I sometimes get tired of tubes and wires,
17 weekly blood test, medications, noisy equipment, but I
18 don't have a choice. It takes all of these things to
19 keep my body going. I literally work all day every day
20 to stay alive. I have hope that science will one day
21 find a cure, and this is the driving force behind why I
22 fight every day to stay alive, only to fight again the

1 next day.
2 Having a complicated, multisystemic disease
3 means that I rely for survival on numerous medications
4 and medical products and on those producing them and
5 those supplying them. This makes me much more
6 vulnerable to recalls and shortages than the average
7 person. I won't be healthy until scientists and
8 doctors can use gene therapy replacement to cure me.
9 But if the medications necessary to keep me alive in
10 the meantime are unavailable, I stand a good chance of
11 being around long enough for that to happen.
12 As I have become aware of just how far
13 reaching this drug shortage is, I have also become
14 aware of new depths of my own fragility. My health is
15 precarious in ways that I hadn't before realized. Now
16 there is little security in the fact that I live with a
17 life-threatening disease in America. There are people
18 dying because of drug shortages in America. I hope I
19 won't be one of them. Thank you for your time and for
20 giving me the opportunity to be heard."
21 (Applause)
22 DR. COX: Thanks you Barbara for sharing Ms.

1 Batalka's experience and story with us. We'll move
2 next to the healthcare provider perspective portion of
3 the program, but before doing so, I just wanted to
4 mention the 11:30 time period that we have available
5 for comments and questions I just thought it would be
6 helpful for folks I'll run through who we have signed
7 up for this time period just so folks can plan ahead.
8 Robert Rifkin, Jan Bult, Marc Stewart, Russell Shipley,
9 C. Allen Black, Kathy Pham, and Joel Zivot are the
10 seven folks that we have. So we ask you to keep your
11 comments to approximately three minutes, and that will
12 be at the 11:30 time period for open comments and
13 questions.
14 And now I'd like to move on to the next part
15 of our program and invite Michael Cohen to the podium.
16 He'll be talking about the impact of drug shortages on
17 medication error from his survey from the Institute for
18 Safe Medicine Practices.
19 MR. COHEN: Good morning, everybody. You've
20 heard a lot of the stories already. It's really a
21 major issue, no question about it. On behalf of most
22 everybody if not everybody in the room, I apologize on

1 behalf of health professionals everywhere for what you
2 have gone through. It's just been a horrible
3 situation.
4 We've always had somewhat of a drug shortage.
5 Now and then these would crop up as Dr. Fox showed
6 before. I guess it was last spring we started hearing
7 more and from pharmacist and nurses mostly from around
8 the country that were running into these situations, so
9 it's over, well over a year already.
10 And it was so bad that we were getting calls
11 left and right, and we actually decided -- I work for
12 the Institute for Safe Medication Practices. It's a
13 nonprofit organization. We're up on Horsham, PA, and
14 we actually operate the national medication error
15 reporting program. And when people report to us,
16 everything that we get goes to the FDA MedWatch
17 program, so we work with the folks in the medication
18 error area here at FDA, and he had some communication
19 with them too. But it was so bad that we decided that
20 we really should be looking into this.
21 We have a newsletter that goes to every
22 hospital in the country basically every two week. We

1 have other outlets a well. We wrote an article about
2 it and told people we were interested in getting
3 feedback, and so we did a survey. And FDA asked me
4 today to go over some of the results of that survey,
5 but you've told the story pretty much already. I don't
6 know that I even need to give my talk so much, but I'm
7 going to go through it anyway. I only have a few
8 minutes, so let me get started. I don't have any
9 conflicts either.
10 This is our newsletter. And by the way, if
11 you go to the September 23, 2010, newsletter on our Web
12 site, we have over a thousand reports of medication
13 errors that came back, mostly serious, and they're
14 classified in different areas in this article. You
15 only see the first page, but there's many other pages
16 as well.
17 I'd like to talk about some of these. Some
18 of these you've heard about already, so I don't have to
19 do that. Obviously, we heard that and we know how well
20 it compromises and delays treatments and procedures,
21 and causes the need for alternative therapies like
22 happened to the Hamlins and others that are sometimes

1 not tolerable compared to the drug that they were used
2 to, and they result in failures as well. Just a couple
3 of these I mentioned. We had a fatal event that was
4 reported in the survey when a patient with an infection
5 called Pseudomonas aeruginosa, which is usually
6 sensitive to many of the antibiotics that are directed
7 at it, but this one was not. It was only sensitive to
8 Amikacin, and Amikacin was unavailable, and this
9 patient died as a result of not getting the antibiotic.
10 We've had situations where people have awaken
11 during surgery because the anesthesiologists were not
12 familiar with the alternative agents that they normally
13 work with and titrated very well and didn't have those
14 problems but couldn't get the drugs that they were used
15 to. What a horrible thing. It happens now and then,
16 but it was happening more often, and we got that kind
17 of feedback.
18 Chemotherapy regimens modified. Absolutely.
19 We've heard that again. I want to tell you about
20 another one too. I had the opportunity of attending an
21 all-day meeting on Friday with the American Society for
22 Parenteral and Enteral Nutrition, and one of the big

1 issue that they have is they basically can't get any of
2 the additive that they normally, and they've had to go
3 to various alternatives, and that's been a major
4 problem, and it has lead to some errors as well
5 including fatal ones, which I'll talk to you on in a
6 minute. So this is a major issue, the whole area of
7 chemotherapy and parenteral as well.
8 The president of the organization, Jay
9 Mirtallo, who's here today, I remember him saying that
10 with most of the drug shortages you can't treat the
11 patient with that drug, but you can give them usually
12 an alternative. And for the most part, it is a
13 suitable alternative although it's not the ideal.
14 With the chemotherapy regimen, for example,
15 we know these are time tested and true, and the
16 research supports that there's a lot of evidence in the
17 literature that these are effective and curative, and
18 you can't use the regular regimen that you would
19 normally use. That's the problem.
20 But with the nutritionals, it's not that you
21 can't treat them. These cause nutritional
22 deficiencies; people are not getting adequate

1 nutrition, and this goes down to the newborns that
2 don't have a functioning gut. So this is a major,
3 major issue in the field of parenteral nutrition.
4 We've had many. Some of them you've just
5 heard about. You heard about the epinephrine overdose.
6 This labeled archaically. It has never been changed
7 despite petitions that have been submitted -- or
8 labeled in terms of the ratio 1:1000 -- not 1 mg
9 necessarily, but the highlight there is 1:1,000 or
10 1:10,000. The syringe that we use intravenously during
11 emergencies is 1:10,000 10 ml. We had mix-ups reported
12 again and again where they gave 10 1 ml ampoules of
13 1:1,000, a massive overdose which basically infarcts
14 your myocardium. So this was one that we had.
15 We had the same one that was mentioned a
16 little bit earlier as well, just a simple mix-ups in
17 the dilution, not knowing how to dilute it properly and
18 giving it straight right out of the ampoule. That also
19 can be for someone that has anaphylaxis, for example,
20 the dose is smaller, and it's usually not even given by
21 IV route. That can cause obviously serious problems
22 and has, and that was responsible for one of the fatal

1 events that we saw.
2 Hydromorphone and morphine. Morphine very
3 commonly used. People are not necessarily familiar
4 although it's widely used in hospital; not everyone is
5 familiar with the dosing of hydromorphone, which is
6 about seven times more potent than morphine. We had
7 name mix-ups occurring when only the alternative
8 hydromorphone was available and doctors were dosing it
9 as if it were morphine, and we had two fatal events
10 reported there.
11 VinCristine and vinblastine, major dosing
12 differences between these two. We had these drugs
13 mixed-up, resulting in a death.
14 And then again, the parenteral nutrition
15 issues. One of the problems we have with this is they
16 can use alternative concentrations; for example,
17 there's a potassium acetate, a sodium acetate which is
18 available in either 4 ml equivalent/ml or 2 ml
19 equivalent/ml. And the problem is you don't just throw
20 this up in a syringe and add it necessarily. They're
21 often used with automated compounders in the pharmacy,
22 and the software that drives that has to be changed. If

1 you can't get your normal concentration, you got to put
2 the new concentration in. This can affect literally
3 scores of patients if that change isn't made. We've had
4 those types of errors as well. So this is not a minor
5 issue by any stretch.
6 And I want to point something else out that I
7 think is critical, and I think FDA could really help us
8 with. They have the ability to go into a pharmacy that
9 compounds IVs. A lot of the hospitals, like with
10 fluorouracil, for example, they are actually starting
11 with active pharmaceutical ingredient, the powder, that
12 they can purchase. And then because there is a
13 shortage, they can supply an actual injection to
14 hospitals. Most of them do a terrific job. They have
15 very exquisite aseptic procedures that they implement.
16 There's even a standard called Chapter 797 of the U.S.
17 Pharmacopeia that actually is required in many states
18 but not all states.
19 And I cannot to this day clearly see anything
20 that articulates what pharmacies are provided with the
21 oversight to ensure that they're making these drugs
22 safely and what pharmacies are not; which are

1 manufacturers that are subject to current good
2 manufacturing practices and which are not. And why is
3 it that our boards of pharmacies in this country are
4 not regulating this critically important safety process
5 called Chapter 797. It isn't being done or not being
6 fully done in most of the states around the country. So
7 this puts our patients in danger.
8 And I think that's a great place to start
9 with FDA and with other agencies is looking at this
10 whole situation to make sure that we have a safe
11 infrastructure for these alternative injectable
12 products that are being made in response to the
13 shortage. We need these organizations, but we have to
14 assure that they're safe, and that's what I wanted to
15 say. These are all situations where fatal events have
16 happened, meningitis, epidural abscesses, bloodstream
17 infections.
18 Just this past year -- or this year, we had
19 nine deaths in Alabama where amino acids for parenteral
20 nutrition were being mixed because they could not get
21 the commercial product. They started with amino acid
22 powders, multiple powders. And the 797 that I talked

1 about was not fully addressed in the pharmacy. There
2 were several violations in that, and unfortunately, it
3 resulted in infections with a containment called
4 Serratia marcescens, and these patients were all
5 bloodstream infections. I think there were 19 in all
6 with 9 deaths. So this is not a minor issue
7 We just had one not because of a shortage but
8 Avastin. And some of these are not
9 necessarily a shortage; it just points out that
10 hospitals and community pharmacies and IV compounders
11 that doing this need to be using the same exquisite
12 aseptic procedures that our pharmaceutical industry is
13 required to use, but that's not happening. The most
14 recent ones were the Avastin blindness in three
15 different cities: Miami, Los Angeles, and Tennessee.
16 They were just reported a few weeks ago. Several
17 people were blinded after these injections were
18 contaminated during preparation in pharmacies.
19 The financial effect of the shortages.
20 Obviously, dramatic increase costs for the
21 time that we're spending, the alternative medications
22 that are not on contract, and so on and so forth. Lots

1 of emotional issues. Doctors arguing with pharmacists:
2 How come I can get it across the street at this
3 hospital but I can't get it here? Maybe this one is
4 using the gray market. We don't know. And that puts
5 people at risk.
6 We don't know where these drugs have come
7 from. Are they counterfeit? Have they been stolen?
8 How have they been stored? There's a risk to
9 purchasing drugs from the gray market, not just the
10 cost. So frustration, anger, mistrust, strained
11 professional relationships.
12 And then we run into these ethical and moral
13 decisions; ethical decision where we have this drug;
14 you have two patients that need it and which one do you
15 give it to. Do you dilute it down maybe and just give
16 part of the dose? That's actually happened, not giving
17 a full dose. These crazy things are happening now,
18 like you said, in our country, in the United States.
19 It's pretty hard to believe.
20 Inability to keep up with important safety
21 initiatives in hospitals, look-alike and sound-alike
22 initiative, double checks, medication reconciliation.

1 And then the sterility issues I mentioned, the gray
2 market issues, where is the drug coming from, how is it
3 stored, etcetera.
4 Delays at updating computer systems and
5 barcoding systems, which I touched on. Possible
6 dispensing and administration errors. Using open
7 medications is another thing we've run into. I've
8 personally seen this. We sometimes are asked to come
9 to hospital and look at their medication system. I've
10 been in ORs where I've seen vials of propofol sitting
11 on top of a drug cart being used as if they're
12 multiple-dose vials. They're single-dose vials, and
13 these are the large vials, and they're used past one
14 hour that even if you kept it under a laminar flow hood
15 it might be safe. That's not the case here. This is
16 used all day long as a multiple dose vial, and it's not
17 under the conditions specified in 797.
18 Using single-dose and unit of use containers.
19 For multiple patients is the issue there.
20 So we've had all these things, and you asked
21 me talk about it, and that's why I bring these up. But
22 I think some of this is addressable.

1 So what I wanted to do now -- shall I just go
2 on to the -- we have a panel, and I'm going to moderate
3 it. The objectives of this panel are -- these are
4 practitioner organizations. We have oncologists,
5 Anesthesiologists, pediatricians, and other specialty
6 setting, some urgency physicians, etcetera, etcetera.
7 And we're going to hear from them. I'd like to mention
8 that we each have five minutes, and we've been pretty
9 good staying on time so far.
10 The practitioners will talk about what the
11 challenges are in their particular field and how the
12 drug shortages have contributed to these challenges
13 that they have. And I'm going to ask each of the
14 participants on my panel to identify yourself rather
15 than go around right now and spend that time, so if
16 you'll identify yourself just before you start. And I
17 will tell you if you go over five minutes, I'm sorry,
18 I'm going to have to cut you off. Thank you very much.
19 Okay. Let's hear first from I guess Ali, Ali
20 McBride. Hi, Ali.
21 MR. MCBRIDE: Thank you so much, Mike. I
22 appreciate it. My name is Ali McBride, and today I'm

1 representing the Hematology/Oncology Pharmacy
2 Association. We are a nonprofit professional
3 organization of over 16,050 members launched in 2004.
4 HOPA's purpose is to optimize the care of individuals
5 fight cancer through the support and advancement of
6 oncology pharmacy practice. HOPA is a leading oncology
7 pharmacy professional organization focusing on efforts
8 to maintain quality and safety in cancer care in
9 disciplinary fashion. Thank you so much.
10 The role of our memberships span from direct
11 patient care to education to research. HOPA leads
12 efforts to ensure the needs and perspectives of cancer
13 patients and their families are maintained regardless
14 of practice setting and that all cancer patients have
15 access to quality and safe cancer care.
16 The grown number of drug shortages is
17 presenting serious challenges to the efforts of HOPA
18 members to provide optimal care to individuals affected
19 by cancer. As has been discussed, the number of drug
20 shortages in critically short supply is increasing at
21 an alarming rate. These shortages threaten the safety
22 and quality of patient care in hospitals and clinics

1 nationwide. In many cases, equivalent therapeutic
2 alternatives are not available or alternatives have not
3 been tested for the intended use or carry increase
4 potential for drug-related complications and increased
5 cost.
6 The potential harm to patients' safety is of
7 paramount concern. These shortages contribute to
8 disruptions in patient care including delay of
9 chemotherapy treatment, cancellation of chemotherapy,
10 changes to different dosing or chemotherapy regimens,
11 and unintended adverse effects. The time and resources
12 focused on the management of these shortages pull
13 healthcare resources away from patient care.
14 Oncology drug shortages have slowed or ceased
15 access to medications with curative intent in a number
16 of cancers. A total of 23 chemotherapy shortages were
17 in short supply in 2010, and 22 reported by August
18 2011. This was the highest number of anticancer agents
19 in short supply since national data collection started
20 in 2003. Chemotherapy shortages have included drugs
21 that are integral for first-line treatment in diseases
22 where cure is the goal.

1 In addition, patients that are being
2 maintained on treatments that have been provided in
3 response are now being changed to different therapies
4 without the proven benefit in the individual patients.
5 In such cases, numerous issues have arisen
6 due to oncology shortages across the nation. The lack
7 of several medications in pediatric ALL regimens, a
8 disease with greater than 95-percent cure rate, hinders
9 patient treatment when an institution is unable to
10 obtain half the drugs in the regimens including
11 vincristine, danuorubicin, and cyclophosphamide.
12 Patients with AML have also had curative
13 treatment delayed or transferred to other institutions
14 due lack of cytarabine for administration of first-line
15 induction chemotherapy or consolidation treatment.
16 Breast cancer patients have been switched to
17 alternative regimens due to lack of doxorubicin.
18 Recently, paclitaxel has been in short supply. The
19 after effects of the shortages has lead to numerous
20 patients with different diagnosis having their
21 chemotherapy delayed or halted due to lack of therapy.
22 Bone marrow transplantations have been put on

1 hold due to inadequate supply of chemotherapy drugs for
2 conditioning regimens.
3 Cancer clinical trials are being affected for
4 both adult and pediatric cancer patients. Clinical
5 trials are being suspended. Patient accrual is being
6 halted, and drug substitutions are resulting in
7 potential problems with the data analysis of the
8 clinical trials.
9 Patients either through the direct loss of
10 chemotherapy regimen or through a supportive-care
11 medication being on short supply are now feeling the
12 consequences of these drugs on short supply.
13 Drug shortages have led to change in
14 chemotherapy regimens which have the potential for
15 increased side effects and unintended consequences. The
16 lack of medication for curative purposes and the
17 treatment of care is simply unacceptable.
18 HOPA is concerned about the effects of
19 oncology drug shortages and continued patient care.
20 Recommendations. HOPA recommends that the FDA and all
21 equivalent stakeholders relevant to the following
22 actions to reduce and eventually prevent drug

1 shortages. And these are advocating for transparency
2 on all issues; consider distribution options for
3 products in short supply; enhance communications among
4 manufacturers, healthcare professional organizations,
5 and the FDA; support product distribution; incentivize
6 manufacturing redundancies as part of the FDA approval
7 process for drugs; require confidential notification of
8 FDA where there is a single API or active
9 pharmaceutical ingredient; notification would apply to
10 informing FDA interruption for these supplies or raw
11 material; and also increasing collaborations with
12 industry, DEA, and FDA; and develop efficient and
13 equitable access programs for patients; as well as
14 maintaining adequate reimbursement for the use of brand
15 named drug therapies or alternative therapies when
16 existing drugs are in short supply; lastly, developing
17 guidelines for oncology regimens when there is a
18 shortage of supply in that regimen.
19 We thank the FDA for seeking HOPA's input on
20 this issue as we hope to continue discussions on
21 answers to resolve the drug shortages.
22 MR. COHEN: Thank you very much. That was

1 perfect. You're right on time. Dr. Lichtenfeld,
2 physician.
3 DR. LICHTENFELD: Thank you, Dr. Cohen. I'm
4 not so sure I'll be good about the time, but I am going
5 to try as hard as I can. Thank you very much. And
6 thanks to everyone for being here today. I'm Dr. Len
7 Lichtenfeld. I'm the Deputy Chief Medical Officer for
8 the American Cancer Society. In terms of conflicts of
9 interests, I have declared that I do have stock
10 ownership in Johnson & Johnson; and of course, the
11 Society does receive grants from various pharmaceutical
12 companies. That information is available on our Web
13 site at www.cancer.org.
14 The Society is a nationwide community-based
15 voluntary health organization that's dedicated to
16 eliminating cancers as a major health problem through
17 prevention, saving lives, diminishing suffering, and
18 through research, education, and advocacy. Without
19 going into all the details, we are nationwide with
20 literally millions of volunteers in 12 geographic
21 divisions.
22 We are very concerned about the impact of

1 cancer drug shortages on cancer patients, and I think
2 it's critically important to point out that these
3 treatments that we use today are based on evidence that
4 has been developed literally over the course of years.
5 I would add that these are not necessarily brand new
6 drugs. These are drugs that have been around for
7 decades, and they still are active and effective in the
8 treatment of cancer. The availability of cancer drugs
9 for patients at their time of need and their time of
10 treatment is critically important as we've heard today.
11 This is a matter of life and death. We have
12 reports of 34 generic drugs on the market; 14 of those
13 are in short supply. And as I've heard today and
14 you've heard, there are likely more than that. And
15 despite the fact that these drugs were developed years
16 ago, they remain critically important in many effective
17 cancer treatments.
18 It's worse in smaller hospitals -- we've
19 heard testimony to that today -- because they don't
20 have the buying power and they may not be in the right
21 locations to get the drugs they need, and that means
22 patients have to go elsewhere. I happen to live in a

1 small town, and we are far from major cancer centers,
2 and the impact of having to travel elsewhere to get
3 medications or other support drugs is a major issue.
4 And workarounds may be okay, but they are not
5 the answer. They are not the same drug. And we do not
6 know, as we've heard today, whether or not
7 administrating a workaround drug is as effective as the
8 actual drug that's necessary for the treatment of that
9 patient.
10 It's a daily nightmare. We've heard actual
11 testimony and obviously very passionate testimony today
12 to that effect. But let me share with you that as a
13 nationwide organization, as Nancy has reported
14 previously, we get calls on a regular basis from
15 patients and families who want to know where do they
16 go, what do they do, and what can we do to fix the
17 problem. Patients want solutions.
18 We want to address this, and we think it's
19 best addressed, as been mentioned here today, through a
20 solution-oriented manner. And there's urgency. This
21 is not something for the -- we have to -- we can't have
22 a committee that's going to report back in two years

1 and then tell us what we need to do four years hence.
2 We need response, and we need effective response now.
3 We need multiple solutions. As we've heard
4 today, we certainly understand there are many complex
5 and intertwined reasons why the shortage exists. We
6 really have to ask why now. These are drugs that I use
7 40 years ago in the treatment of patients with acute
8 leukemia that are still effective today. They are
9 lifesaving, and the reality is suddenly after all of
10 these years those drugs are not readily available.
11 So we call on the industry to act
12 expeditiously to provide the public with a full
13 understanding of why and how this has arisen, and until
14 these causes are better understood, there are several
15 steps that we think should be taken. For example, the
16 Federal Government should expand its collection of
17 information on the underlying causes of the current
18 drug shortages; and patients and clinicians, as we've
19 heard today -- we would emphasize and underline this --
20 need better information about drug shortages and better
21 options for purchasing the drugs they need for
22 treatment.

1 We need to compile available inventories of
2 drugs that are in short supply including where
3 shortages exist. We need to work with interested
4 parties as information become available about the
5 causes of specific shortages to resolve those
6 shortages. Adequate production to meet demand in the
7 near term could be leveraged by the National Cancer
8 Institute infrastructure for drug development to
9 provide short-term supplies for individual cancer
10 drugs.
11 And finally, we encourage manufacturers,
12 distributors, and other stakeholders in the drug
13 manufacturing and supply process to voluntarily step
14 forward to help work expeditiously to find short- and
15 long-term solutions to the critical problem.
16 We heard today and we've heard previously
17 about the gray market. And frankly, aside from the
18 concerns about safety, it really raises some serious
19 questions about where our priorities are in this
20 country that patients should have to pay thousands of
21 times more than the drug cost in order to get something
22 that they need to save their lives.

1 Gray markets arise when there are
2 misallocations and underproduction and raise the
3 possibility of price gouging or hoarding, and that
4 further exacerbates the seriousness of this problem.
5 There is an extraordinary need to look at the root
6 causes and take quicker actions to stem the drug
7 shortage crisis. And we ask the manufacturers,
8 distributors, and other participants in the drug
9 manufacture process develop immediate and long-term
10 solutions to address this horrible crisis for cancer
11 patients, and I can't ignore --
12 MR. COHEN: Dr. Lichtenfeld, that's --
13 DR. LICHTENFELD: -- a closing very briefly -
14 -
15 MR. COHEN: -- that's it.
16 DR. LICHTENFELD: -- if I may because I've
17 carried this message from a number of people that I've
18 talked to --
19 MR. COHEN: Wrap it up.
20 DR. LICHTENFELD: Very briefly. When you
21 talk to a cancer expert in leukemia and he says I
22 cannot get cytarabine to treat my patients and there is

1 no substitute, as happened to me this weekend, I carry
2 that message to this panel, to the FDA, to everyone in
3 this room, it's not acceptable.
4 When a colleague of mine has a wife -- and
5 he's no different than a lot of other folks -- who's
6 being treated for metastatic ovarian cancer and her
7 last hope for survival is to get a drug that they
8 cannot get and he reaches out to everyone he knows
9 across the country begging to do whatever is necessary,
10 those people stand not as individuals, they stand as
11 representatives for a problem that has occurred, is no
12 longer acceptable; and we must pull together to find
13 solutions that are effective for the patients we take
14 care of and the patients we care for. Thank you.
15 MR. COHEN: Thank you, Dr. Lichtenfeld. I'm
16 sorry. We have to move on.
17 DR. LICHTENFELD: That's okay. I wish I
18 could give you another five minutes. You sounded
19 great. It was great. Dr. Solberg.
20 DR. SOLBERG: My name is Larry Solberg. I
21 practice hematology in Jacksonville, Florida, at Mayo
22 Clinic in Florida. I'm here representing the American

1 Society of Hematology. I'm the Chair of
2 their practice committee. And our Society has 16,000
3 members, and the clinicians in our Society treat
4 leukemia, lymphoma, bone marrow transplant, malignant
5 disorder. But we also treat a wide range of benign
6 disorder: Sickle cell disease, coagulation disorders.
7 I thank you for this invitation of our Society to make
8 some remarks. I have no disclosures and no slides.
9 Our remarks will fall in to general areas:
10 First, how this is affecting our patients and
11 clinicians; and then some of our suggestions.
12 As I've listened to this over the past year
13 in this conference, I personally believe we're facing a
14 tsunami of risks here. I use the work tsunami because
15 what if what we're seeing is the earliest wave
16 approaching the shores of our medical system, what is
17 to follow. We know the destructive force of a tsunami
18 is what to follow. So I agree with Rear Admiral that
19 this is something affecting all of us.
20 Turning to how this has affected our
21 patients. We have found that they have had increased
22 suffering, and certainly it's affected the practice of

1 hematology. You've heard much of this. Let me talk
2 about scheduling. It is of course very upsetting to a
3 patient to be told one may have to start their
4 treatment a few days later; even if there's no clinical
5 impact on their course, it's very upsetting to hear
6 that. But think of what the clinician and the
7 physician and the pharmacist are dealing with. Many of
8 these regimens exists over six months, and so what if
9 one has drugs for three cycles. What about cycles 4,
10 5, and 6? This is a real crucible.
11 I think a suggestion to the FDA and those of
12 you who have maintained these registries is that point
13 of service if one is seeing a patient now I don't need
14 to know next week. We need to know now when is that
15 drug going to become available, how much of it will
16 become available.
17 You've heard these other two points that
18 affect our practice. Choosing a regimen that may be as
19 effective but with a great toxicity profile, which we
20 think has happened; or being forced to choose a regimen
21 for first line of treatment that may not have been
22 compared front to front to the standard treatment, and

1 then one is engaging on perhaps a less effective
2 treatment in treating a patient.
3 I also want to mention clinical trials.
4 Normally, we're able to discuss with patients "You have
5 treatment option A, standard treatment; B, good
6 risk/bad risk, but we also have a clinical trial. In
7 some cases, these have been taken off the table. This
8 reduces patients' choice. It impedes science.
9 Now turning to our recommendations. There
10 are many causes, many things needed. Our initial
11 comments are around really the FDA. We share the
12 urgency here. We think steps need to be taken now. We
13 note that having four employees in the Drug Shortage
14 department may not be enough given the level of this
15 challenge.
16 Some specific recommendations are improving
17 communications between the FDA and stakeholders. I
18 think it would help if there were specialty-specific
19 list servers. And again, the clinicians need to know
20 when is it could become available. This is hard
21 information to get, but that's what needed.
22 We think that the current configuration of

1 FDA authority and policy is not sufficient, that where
2 you are now should change. And we support the
3 Preserving Access to Life-Saving Medications Act, S296,
4 and the HR2245 version, as a trajectory for trying to
5 improve that.
6 We think you should continue examining to see
7 if any of your testing requirements around
8 methodologies may contribute to the problem of drug
9 shortages and looking at drug availability. We think
10 that developing a national drug registry would be
11 useful, and we wonder if expanding the orphan drug
12 status in this situation might help manufacturers to
13 continue producing single-source older drugs.
14 This current situation -- I think in medicine
15 we have situations where we want zero tolerance. I
16 think we all would want zero tolerance for this type of
17 drug shortages.
18 There is much to be done here. We thank you
19 for the opportunity to comment. We do have a letter
20 with more detailed placed in the docket. Thank you.
21 MR. COHEN: Thank you very much. Karen
22 Hagerty.

1 DR. HAGERTY: Thank you. Good morning,
2 everybody. It's a real privilege to be here. My name
3 is Karen Hagerty. I'm with the American Society of
4 Clinical Oncology, and we represent nearly 30,000
5 members, physicians, and other healthcare professionals
6 that are involved in the care of patients with cancer
7 and in research into promising new treatments.
8 After the passionate articulations you just
9 heard from Dr. Lichtenfeld and others, there isn't too
10 much that I can add to what they've said. They've
11 really sort of painted a great picture of what it's
12 like, but I do want to give you somewhat of an idea
13 what it's like sort of out in the day-to-day practice
14 in the community oncology practice.
15 We've heard a lot today from our colleagues
16 from in-hospital setting and how this is impacting
17 institutions and hospitals. Certainly, it's having the
18 same if not a worse impact in a lot of community
19 setting partly because some of these practices are
20 simply not large enough to have the purchasing power to
21 get these drugs when they're in shortage, so it's
22 definitely a real problem for many of the community

1 practices.
2 And we first started hearing from our members
3 -- I think others have mentioned -- around spring of
4 last year, spring of 2010, was when this problem seemed
5 to become really reaching a crescendo. And so then, of
6 course, ASCO became involved with ASHP and ISMP and
7 others at the Drug Shortage Summit last year, and
8 you'll be hearing a lot more about that a little later
9 this afternoon. So I won't go into too many details
10 there.
11 Our members call us a regular basis. They're
12 angry. They're frustrated. They're frightened for
13 their patients. They want to know when this is going
14 to be fixed and what we're going to do to fix this
15 because patient care is really the ultimate thing
16 that's on the line here.
17 I did just want to expand briefly on the
18 issue of clinical trials, which has also been
19 mentioned. Recall for most cancer clinical treatment
20 trials there is not a placebo arm, so the issue that
21 we're getting into with clinical trials isn't
22 necessarily that the experimental drug, if there is one

1 in the trial, is not available, it's the fact that the
2 standard of care arm to which the new treatment is
3 being compared is not available. And has been touched
4 on by others, not only is this a disservice to the
5 patients that are enrolled in the trial, but it leads
6 to later problems down the road with data analysis when
7 you've had drug substitution or you've had trial delay.
8 That's something else. It's obviously of tremendous
9 concern to us.
10 You have practices where physicians and their
11 professional staff are having weekly meetings to look
12 at their inventory of drug and essentially have to
13 triage which patient is going to get which drug if
14 there is no more drug coming in the door. This is an
15 untenable situation for both health professionals and
16 patients. And I will echo, it's been said by others
17 that this situation is simply unacceptable for patient
18 care and something needs to be done about it right now.
19 I will hold off on discussing and
20 recommendations until later this afternoon. Thank you.
21 MR. COHEN: Thank you very much, Dr. Hagerty.
22 Arnold from the American Society of Anesthesiologists,

1 American Association of Nurse Anesthetists.
2 DR. BERRY: Yes. Thank you. I do have
3 slides. I wonder if the projectionist could put those
4 up and advance them for me.
5 While those are coming up, I'm Arnold Berry.
6 I'm Vice President for Scientific Affairs for the
7 American Society of Anesthesiologists. The ASA is the
8 medical specialty organization for anesthesiologists
9 who are physician practicing anesthesia, critical care,
10 and pain medication. I have no financial disclosure to
11 mention related to my presentation.
12 In order to understand the scope of the
13 impact of drug shortages on anesthesiologists, I think
14 it's important to understand that anesthesiologists now
15 work outside their traditional locations of the
16 operating room and labor and delivery. We now provide
17 anesthesia and sedation for endoscopy, in cardiac cath
18 labs, and for radiology procedure. Most surgeries now
19 occur in free-standing ambulatory surgery centers.
20 These are not often connected with hospitals. These
21 are not associated with hospitals and obtain drugs in
22 other ways from large hospitals that we've been hearing

1 about today.

2 Also, many of our members practice in surgeon

3 or dental offices providing anesthesia one on one with

4 physicians. We also work in pain clinics and in

5 critical care units.

6 In order to understand the impact of drug

7 shortages on our members, we conducted a survey this

8 past April. We received responses from approximately

9 1,400 anesthesiologists, and almost all of them had

10 experienced a drug shortage during the previous year.

11 It was interesting that at the time of the survey 90

12 percent said they were currently having a shortage of

13 at least one or more drugs.

14 The specific drugs in shortage during the

15 past year are listed here. We've heard a little bit

16 about propofol already, and I'll mention a bit more

17 about it in just a minute. But in addition to

18 propofol, many of the bread-and-butter drugs that we

19 use on a daily basis are affected as well. In

20 additional succinycholine and epinephrine that were in

21 critical incidents were in short supply for many of our

22 members. And not having these drugs when severe

1 emergencies occur result in failure to rescue and
2 severe consequences to the patients.
3 From this survey, about half of the
4 anesthesiologists reported that they had changed their
5 anesthetic management in some way, and they felt that
6 shortages resulted in less optimal patient outcomes
7 including longer operating room times or recovery
8 times.
9 What was most significant was that 10 percent
10 reported that they had postponed or cancelled
11 procedures because of lack of drugs. If you think
12 about a patient who has come for surgery, their family
13 has come in from out of town; they've arranged care for
14 their children. The societal impact of these
15 cancellations is significant.
16 Propofol has been mentioned previously. It's
17 now the most frequently used drug to induce anesthesia
18 and to provide sedation for diagnostic and therapeutic
19 procedures. The pharmacologic profile of propofol is
20 such that it provides quick anesthesia with very quick
21 awakening, and in the ambulatory surgery setting today,
22 it's become our go-to drug.

1 Other drugs can be used for induction of
2 anesthesia, but they have less optimal characteristics
3 and result in outcomes which lead to patients being
4 unsatisfied with their care. This includes prolonged
5 awakening, longer stay in the recovery room prior to
6 discharge, and increased post-operative nausea and
7 vomiting.
8 So although anesthesiologists are trained to
9 safely use multiple drugs and can often find
10 alternatives when there are drug shortages, often there
11 are unavoidable consequences of these. Some decrease
12 patients' satisfaction but others are significant
13 adverse outcomes including death. These are often
14 critically ill patients who need these rescue drugs
15 which have been in short supply.
16 There has also been an impact of drug
17 shortages on healthcare cost; that is, we've heard
18 today about alternative sources of drugs and the way
19 that practitioners have to pay increased prices when
20 drugs in short supply are purchased through an
21 alternative source. Longer procedure and recovery
22 times drive up healthcare cost to the healthcare

1 system. And there's societal and healthcare cost for
2 cancelled and postponed procedures.
3 So from the data that I've presented today, I
4 hope that you see that there has been significant
5 impact on the practice of anesthesiology in terms of
6 our patients and the healthcare system.
7 The ASA has been one of the organizations
8 involved with the Drug Shortage Summit Workgroup, and
9 our recommendations will be presented later today in a
10 presentation from that group. Thank you.
11 MR. COHEN: Thank you very much. We're going
12 to move on to pediatrics now and Dr. DeWayne Pursley.
13 DR. PURSLEY: Thank you, Dr. Cohen. I may
14 need to request an additional 30 seconds of indulgence
15 as I speak to the impact --
16
17 MR. COHEN: Think about it. (chuckles)
18 DR. PURSLEY: -- of the shortages and
19 possible solutions for our country's children.
20 My name is DeWayne Pursley, and I'm Chief of
21 Neonatology and Director of the Neonatal Intensive Care
22 Unit at Beth Israel Deaconess Medical Center in Boston,

1 Massachusetts. I chair the American Academy of
2 Pediatrics, that is the AAP, Section on perinatal
3 pediatrics, and I'm here today in an official capacity
4 representing the AAP, a nonprofit professional
5 organization of 60,000 primary care pediatricians,
6 pediatric medical subspecialists, and pediatric
7 surgical specialist. I want to thank the FDA for the
8 opportunity to provide comment on drug shortages.
9 As a practicing pediatrician, I've seen
10 firsthand the impact of drug shortages on the practice
11 on pediatrics. Shortages, discontinuances, or
12 interruptions in the pediatric drug supply has and will
13 continue to put our patients are risk. The AAP has
14 worked for decades to ensure that medicines used in
15 children are studied in children. The physiology of
16 children is different than that of adults, and as such,
17 we must wherever possible have the benefit of age-
18 specific therapeutic safety and efficacy data.
19 Two laws, the Best Pharmaceuticals for
20 Children Act, BPCA, and the Pediatric Research Equity
21 Act, PREA, has enabled giant strides toward achieving
22 this goal. The Academy is greatly appreciative of its

1 partnership with FDA on these two laws and is proud
2 that to date because of these laws nearly 400 drugs
3 have been relabeled with pediatric information.
4 The AAP looks forward to working FDA to renew
5 and strengthen these laws when they are up for
6 reauthorization in 2012.
7 In recent years, much like Abigale Hamil's
8 and her fellow patient Makayla's experiences, many of
9 the U.S. drug shortages had directly impacted children.
10 Exactly two years ago, there was a widespread national
11 shortage of erythromycin ophthalmic ointment. Four
12 million children each year need this ointment for
13 prophylaxis. Some states mandate it. At the time of
14 the shortage, the two alternative products were no
15 longer available in the U.S. The Government did not
16 appear to have anticipated the shortage, and it took
17 pressure from the AAP and others for Federal agencies
18 to develop and release recommendations for an
19 alternative prophylaxis regimen.
20 More recently, my colleagues and I in
21 neonatology have experienced shortages of component
22 ingredients for lifesaving treatment for neonates,

1 total parenteral nutrition, TPN, which is used in
2 babies who cannot yet eat and have no alternative
3 nutrition source. For newborns who rely on TPN
4 intravenously as their source of nutrition availability
5 of these component ingredients is truly a matter of
6 life or death.
7 Drug shortages impact general pediatricians
8 and subspecialists alike. At present, pediatric
9 rheumatologists are reporting shortages nationally of
10 injectable methotrexate. But whether it's the propofol
11 shortages that have had a profound impact on pediatric
12 anesthesiology or persistent shortages of antibiotics
13 such as IV preparations of trimethoprim,
14 sulfamethoxazole, or Amikacin, drug shortages are
15 increasingly more common.
16 It is worth noting that the IV preparations
17 of pediatric medicines appear to be disproportionately
18 overrepresented. The AAP believes that a comprehensive
19 solution to drug shortages must include provisions that
20 prevent the shortage from occurring in the first place.
21 We urge FDA to develop and maintain a list of critical
22 medications that should specifically include

1 medications used in pediatric population. For
2 pediatrics, such a list should not be limited to the
3 labeled indication of the product since so many
4 products used in children, especially neonates, are not
5 labeled for their use.
6 Among the products that should be included in
7 the critical drugs list are those that come from a sole
8 manufacturer. Once this critical medications list is
9 developed, FDA working with other Federal partners
10 should determine how much of the product is necessary
11 to have on hand to meet demand in advance of a
12 potential shortage. Then, FDA and its partners should
13 establish a mechanism for the purchase and storage of
14 advanced supply of the critical medications on this
15 list.
16 AAP recommends FDA and its Federal partners
17 consider the creation of a national critical medication
18 stockpile using the strategic national stockpile as a
19 model.
20 FDA should develop and maintain a database
21 containing information about the domestic and foreign
22 manufacturers for all the items on the critical

1 medications list regardless of whether their products
2 are approved in the U.S. Over time, FDA should take
3 step to work with manufacturers so they can meet U.S.
4 standards for safety and efficacy. Other
5 efforts to increase supply should be explored.
6 The AP is concerned about inconsistent
7 distribution or maldistribution of products that are in
8 short supply. We urge the FDA and its Federal partners
9 to establish a process to ensure fair and equitable
10 distribution of products that are experiencing a
11 shortage. We also hope there will be strong national
12 safeguards in place to protect against hoarding or
13 price gouging.
14 The AAP is deeply concerned about FDA's
15 current system for alerting pediatricians to potential
16 or actual shortages of pediatric products. The current
17 system is simply too passive. We urge FDA to develop a
18 system for real-time, bidirectional exchange of
19 information because in some cases healthcare providers
20 may be the first to learn about a change in supply. The
21 AAP has mechanisms to quickly disseminate such
22 information to our 60,000 members. Increasing staffing

1 and resources at FDA's office of drug shortages is also
2 critical.
3 Finally, once the shortage has occurred, we
4 urge the FDA to work more quickly with companies to
5 restore their ability to manufacture safe and effective
6 products. Special attention and urgency should be paid
7 to the products on FDA's critical medications list.
8 Because of the lack of supply for certain critical
9 products can represent a threat to the public health,
10 we recommend FDA explore the use of authorities such as
11 emergency use authorization or personal importation
12 provisions to allow for additional supply to enter the
13 U.S. market under time- and quantity-limited
14 circumstances.
15 There have been instances where no new supply
16 is available and no alternative manufacturer exists.
17 Therefore, FDA and its Federal partners should work
18 much faster to identity recommended alternative
19 therapies and communicate them broadly to the public,
20 especially the provider community. Wherever possible,
21 the FDA and its Federal partners should utilize outside
22 subject matter experts when developing these

1 recommendations or guidance for alternative therapies
2 in children.
3 The AAP looks forward to working with FDA and
4 others on the critical issue of drug shortages. Thank
5 you for the opportunity to speak today.
6 MR. COHEN: Thank you, Dr. Pursley. We have
7 some specialty settings: Department of Veterans
8 Affairs, American College of Emergency Physicians, and
9 research hospital, St. Jude's. Let me call on Dr.
10 Vincent Calabrese first.
11 MR. CALABRESE: Hi, thank you. Thanks for
12 the opportunity to provide some comments regarding the
13 drug shortages in the Department of Veterans Affairs.
14 My name is Vinny Calabrese, and I work in the National
15 Pharmacy Benefits Management Office in the VA. And
16 this just shows I don't have any conflicts of interest,
17 and my travel and accommodations are paid for through
18 the VA.
19 I'm going to briefly go through a little bit
20 of background about the VA for those who aren't aware,
21 a few examples on the effects of shortages on
22 outpatients and inpatients in the VA, some of the

1 resources we use, some of the actions we take to help
2 manage the shortages, and some recommendations.
3 VA is a closed system. It's nationwide. We
4 have hospitals around the country, about 152 hospitals
5 and just under 1,000 clinics. We have about 22.7
6 million total veterans, and most of those are elderly
7 male population. And of those 22.7, about 8.3 are
8 actually enrolled for care, and about 4.7 million
9 actually use the pharmacy benefit.
10 As far as volume of outpatient prescriptions,
11 about 258 million prescriptions per year dispensed
12 through the VA in terms of 30-day supplies. And 82
13 percent of that goes through our CMOP, which is our
14 consolidated mail-out patient pharmacy, and only about
15 18 percent are dispensed through our local facilities.
16 And the reason for using the CMOP, the mail-
17 out pharmacy, is the high efficiency and accuracy we
18 can extract from those plants, and there are seven
19 plants across the U.S.
20 So effects on outpatients really centers
21 around the fact that we have an efficient system that's
22 very sensitive to the supply chain, so anything that

1 interrupts that supply chain really can results in
2 delays in patient care. The way it usually works is
3 when veterans request their prescription they typically
4 request is as soon as they get their prescription
5 refill, and it's cued to be routed to the CMOP and
6 filled so that they receive them within 10 days.
7 In order for the system to work efficiently,
8 the mail-out pharmacy has to have that prescription
9 filled and out the door in 48 hours; and by out the
10 door, I mean out to the mail delivery whether it's UPS,
11 Fed-Ex, or U.S. Postal Service.
12 If the CMOP can't fill that prescription,
13 then they have to send it back to the facility, and
14 then the facility is faced with the workload of having
15 to fill that prescription and potentially finding a
16 source. So that potentially delays veterans in getting
17 their medications when they need them.
18 An example of the effect on inpatients -- and
19 you've heard it before -- when we have a big shortage
20 on anesthesia drugs, particularly succinylcholine,
21 we're actually having surgeon cancellations in the VA.
22 And what we have to do to alleviate that problem is to

1 actually have the head of anesthesiology construct some
2 guidance for the field -- actually for their own staff
3 -- with input from surgery and PBM pharmacy. And we
4 came up with strategies such as alternatives that can
5 be used, options that can be used such as rocuronium
6 where it's appropriate and also strategies to conserve
7 the supplies that we have. And that would include
8 preserving succinylcholine for absolute emergencies
9 when all other options can't be used that are
10 clinically appropriate; and also drawing up
11 succinylcholine in syringes under a laminar flood hood
12 which extends the stability and the shelf life rather
13 than drawing it up as the procedure site.
14 At the VA we use the Web site that I'm sure
15 everybody's aware of both the FDA's Web site here, and
16 the next page is the ASHP Web site. We make very good
17 use of those Web sites. They give us a lot of
18 information, but we still have to go and do our own
19 research when we're trying to plan for a drug recall.
20 These are some of the actions we take.
21 Certainly what everybody probably does is to look in
22 the area both public and private hospitals to find out

1 where we can get additional stock for emergencies. And
2 we have found situations where some private hospitals
3 or small hospitals chains actually have excess stocks
4 during a shortage; either they're from contracts or the
5 gray market; for some reason, we're able to get them.
6 So we don't hold back in trying to call around.
7 We also can coordinate sharing between our
8 own VA hospitals either centrally from the PBM level
9 nationally or we have mail groups that the pharmacy
10 purchasers can collaborate and find out who has extra
11 and who can share.
12 We've also consolidated our dispensing and
13 purchasing into one mail-out pharmacy for efficiency
14 purposes and to be able to track who gets what.
15 We also have reduced the prescription
16 quantity when we have a severe shortage from a 90-day
17 supply to a 30-day supply because we use a lot of 90-
18 day supplies just for cost effectiveness both for labor
19 and for efficiency.
20 MR. COHEN: You have about 30 second, okay.
21 MR. CALABRESE: Okay. So what we do we also
22 put together our own shortages report; it's published

1 as part of a weekly pharmaceutical newsletter, and it
2 looks very like you'll find on the Web sites.
3 But we have to do additional work. We have
4 to call the companies and find out the most updated
5 information. We look in our prime vendor wholesaler,
6 see what's available; look and see what's available
7 direct. And the action may be in part to work with the
8 provider to find alternatives like we do with
9 anesthesiology.
10 Here are just a few recommendations. We
11 appreciate the FDA's actions to help remedy the
12 situation, and we have some ideas to enhance those
13 initiatives. One: Foreign importation could be a
14 problem for VA and other Federal agencies because we
15 have Federal Acquisition Regulations that can make it
16 difficult for us to purchase from foreign countries.
17 And certainly, even if we had a way to do that,
18 sometimes the reaction time isn't fast enough because
19 there are times when you need to make a decision within
20 a day or even hours to get stock that's available.
21 So we recommend the FDA work with Federal
22 agencies and VA to see if there is anything that can be

1 done ahead of time to help alleviate that problem so
2 that we can take advantage.
3 MR. COHEN: I'm going to have to stop you --
4 MR. CALABRESE: Okay.
5 MR. COHEN: -- I'm sorry. And just one more
6 comment.
7 MR. CALABRESE: And just one more comment.
8 MR. COHEN: Of course.
9 MR. CALABRESE: We support what FDA is doing
10 to help with early notification. Anything that could
11 be done to notify FDA and organizations and the public
12 as soon as possible so that we can plan, that would be
13 the best.
14 MR. COHEN: Thank you.
15 MR. CALABRESE: Thank you. And now Dr. Blum
16 and then Dr. Hoffman. You each will have five minutes.
17 DR. BLUM: Hi, I'm Rick Blum. I'm here
18 representing the American College of Emergency
19 Physicians. That's not important for today. What is
20 important is for the last 30 years I have practiced
21 emergency medicine clinically in a large relatively
22 sophisticated Level 1 trauma center that's the tip of a

1 hospital system in a small rural state, but this is a
2 big place, relatively sophisticated place. And it's
3 important because the story I'm going to tell occurred
4 a little less than a year ago.
5 It was a busy night shift. The place was
6 full. The hallways were lined, and we were going to
7 get a multipatient trauma in, six patients from a coal
8 truck hitting a van with people in it. Several of the
9 patients are critically ill. We work through that
10 process with our trauma team. Several of those
11 patients went to the operating room, typing up our
12 anesthesia department.
13 They saved the best for last though. The
14 last was a patient who had been entrapped in this
15 accident for about an hour. He was critically ill. He
16 was head injured. He was intoxicated. He had multiple
17 facial fractured. He likely had an intercranial
18 hemmorrage. He likely had a cervical spine fracture.
19 He came into my emergency department unintubated. He
20 had a big wiry beard. He had multiple broken bones in
21 his face. This is as nasty an airway as you can
22 imagine, and my anesthesia friends I think would

1 probably second that. He has a full stomach. He's had
2 no preop. I have to him drug to intubate, protect his
3 airway so we could do a rapid CAT scan and resituate
4 him.
5 I'm a been-there-done-that sort of emergency
6 physician, but this one is a sphincter-tightening sort
7 of moment. You lean on the tools that you've used for
8 30 years, and for 30 years, I've used a paralytic drug
9 that has very rapid onset, has very short duration
10 because I know in the gentleman if I can't get him
11 intubated I'm not going to be able to bag him. He has
12 no face to get a seal with a bag. This is a deal where
13 I paralyze him and then I get him intubated or he dies.
14 It's as simple as that. I can't preoxygenate him
15 because of his physiologic status. And I turn and I
16 ask for the standard dose of succinylcholine, and I
17 have the nurse tell me "We don't have succinylcholine.
18 What else do you want?"
19 I've used succinylcholine hundreds of times
20 over 30 years, maybe thousands actually. So I go to
21 the next closest drug, which I've used maybe a dozen
22 times. It's kind so fast, much longer duration. We

1 don't have that either. Because of the succinylcholine
2 shortage, we've used up our relatively small stocks of
3 that drug. So I go to a third drug, very long onset,
4 very long acting. Fortunately, we got him intubated.
5 We were able to preserve his life; took years off of
6 mine.
7 (Laughter)
8 DR. BLUM: He got to the operating room and
9 thing went okay. I left the room only to be yelled at
10 by the orthopedists who were waiting to reduce the hip
11 on an adolescent patient from the same accident. A hip
12 dislocation is an orthopedic emergency. The longer
13 it's out the greater the chance of aseptic necrosis of
14 the hip. He needed to have deep sedation. I needed
15 something sort acting because the place is crazy; my
16 nurses are at the limit. I can't to have a nurse, a
17 doctor, and a resident all in the room for an hour
18 while we give a long-sedating drug.
19 So I pull out another favorite tool that I've
20 used for years: Propofol, short acting, lasts about 5
21 or 10 minutes, works really quick. We don't have
22 propofol. Okay. So we go to plan B, and we tie up

1 people for an hour while we wait for the next best drug
2 to wear off. The orthopedist put the hip back in in a
3 few minutes, but I was stuck in the room for an hour
4 waiting to recover the patient from the much longer
5 acting drug.
6 While this all was going on, a patient came
7 in with status epilepticus. You know how this story is
8 going to end. I give him Ativan to stop the seizure,
9 but it doesn't stay stopped. I give him some more; it
10 doesn't stay stopped. I want to bolus him with another
11 drug to keep the seizures at bay. We don't have that
12 drug. So I actually had to do general anesthesia on
13 him, which is kind of the final option for a status
14 epilepticus patient.
15 Anyway, the point is not much flusters me in
16 emergency medicine anymore, but I have to tell you I
17 left that shift shaking my head, okay. Emergency
18 medicine -- I don't have a solution for this, but I
19 could tell you this is a silly problem that we need to
20 fix. On one side, we have a market that's large and
21 stable. On the other side, we have manufacturers that
22 are in the business of making money. I'm just a dumb

1 doc, but I have to believe that between those two
2 things there has to be a barrier that we need to tear
3 down. And we need to do it now.
4 MR. COHEN: Thank you, Dr. Blum. Finally,
5 Dr. Jim Hoffman from St. Jude's.
6 MR. HOFFMAN: Thank you for the opportunity
7 to speak today. I have no conflicts of interest to
8 disclose. I'm the Medications Outcomes and Safety
9 Officer at St. Jude Children's Research Hospital, so I
10 lead medication safety efforts across the hospital.
11 The mission of our hospital is to advance
12 cures and means of prevention for pediatric
13 catastrophic diseases through research and treatment.
14 Our areas of focus are childhood cancer, nominally
15 hematology such as Sickle Cell Disease and hemophilia
16 and infectious diseases. So my comments will focus on
17 the impact of drug shortages on both research and
18 treatment for children with these catastrophic
19 diseases. Since we've heard a lot already about the
20 impact of drug shortages on cancer patients and other
21 patients, I'll focus most of my comments on the impact
22 on clinical trials.

1 The slide I have up just reflects the St.
2 Jude experiences with drug shortages, and it's very
3 consistent what Erin Fox showed of how chemotherapy
4 shortages have really increased over the last two
5 years.
6 The next slide lists some of the notable
7 shortages of impact over the last couple of years at
8 St. Jude. We've heard a lot about total parenteral
9 nutrition already. One thing that I want to make sure
10 I clear this is a very complex and high-risk medication
11 to prepare, and hospitals and other sites that prepare
12 total parenteral nutrition we really seek to
13 standardize our processes on the shortages. Really,
14 every component of TPN has been in short supply, and so
15 the shortages have made us constantly change our
16 standardized practices, which really is concerning from
17 a medication safety perspective.
18 Also, we did have a patient with a
19 multivitamin shortage. The patient was taking oral
20 multivitamin because the IV multivitamin was not
21 available, and the patient developed a thiamine
22 deficiency, which fortunately was reversed, but it

1 resulted in a lot of anxiety and hospital admission.
2 As others have mentioned from the cancer
3 perspective, we are forced to make prioritization and
4 substitution decisions on a regular basis for
5 chemotherapy shortages. We often have to use
6 alternative agents and agents where there is less
7 evidence. We are concerned about the long-term impact
8 of using alternative agents on children with cancer.
9 Now from the clinical trial perspective, many
10 of the advances that we've made in pediatric childhood
11 cancer are due to the excellent participation of these
12 patients on clinical trials; 60 to as many as 85
13 percent of pediatric cancer patients are enrolled in
14 clinical trials, and this is really advanced cures.
15 From the clinical trial perspective,
16 obviously everyone works very diligently to meet all
17 the clinical research regulation. Each shortage
18 prompts a tremendous amount of work and documentation
19 to continue to comply with regulations as changes are
20 constantly being made. Both St. Jude and the
21 Children's Oncology Group, which is the primary
22 cooperative group for childhood cancer, have had to

1 create guidance for investigators for how through drug
2 shortages from the clinical trial perspective.
3 This slide lists some of the specific
4 shortages that have impacted clinical trials. We've
5 heard about the cytarabine shortage and how there
6 really is no alternative, and we are aware that
7 enrollment on frontline AML protocols have been
8 suspended for pediatric oncology.
9 Mechlorethamine or nitrogen mustard, a
10 shortage that hasn't been mentioned is an important
11 drug in all of our Hodgkin's lymphoma protocols, and
12 these protocols had to be modified along with the
13 collaborating site with St. Jude.
14 Also, daunorubicin, which we heard about,
15 that's a current shortage and challenge for us, and
16 we've had to prioritize two ALL patients -- AML
17 patients. We've substituted idarubicin, where there is
18 less data again.
19 Again, from the perspective of the clinical
20 trials perspective, I want to point out that the
21 Children's Oncology Group, which we are members of and
22 participate, we are aware that at least 85 COG clinical

1 trials have been impacted by drug shortages. And I
2 have no doubt that data analysis interpretation as
3 those clinical trials mature will be much more
4 challenging due to drug shortages and the tremendous
5 number of deviations and unique amendments that have
6 had to be made in those clinical trials.
7 Finally, I'll just close with a large
8 perspective. While we've talked about drug shortages
9 and particularly chemotherapy drug shortages really
10 increasing over the last couple of years, this has been
11 a long-term challenge for pediatric oncology. Acute
12 lymphoblastic leukemia is the most common childhood
13 cancer. Fortunately, cure rates are up to 90 percent,
14 and we use 10 drugs to cure patients. And over the
15 last decade, 8 of these 10 drugs have been in short
16 supply.
17 So thank you again for the opportunity to
18 illustrate the impact of drug shortages on both
19 research and treatment for children with catastrophic
20 diseases.
21 MR. COHEN: Thank you very much, Dr. Hoffman.
22 Okay. We are going to take a few more minutes even

1 though we should be ending at 11:30. We've been given
2 the opportunity to take a few more minutes anyway to
3 have some discussion on this. And the idea here was to
4 come up with challenges, maybe the top three challenges
5 that FDA needs to help you with. And I'm actually
6 hearing several things.
7 There's been a few that's have been
8 recurrent. One is more effective communication and the
9 idea of bidirectional communication. And of course,
10 there is Web site information, but you're saying that
11 that really isn't adequate enough, that you'd rather
12 have bidirectional communication and more rapid
13 communication between FDA and stakeholders.
14 Now they also heard more information on when
15 -- and I'm not sure the FDA can actually do these
16 things or do them on their own. They may have to be
17 working with other agencies. That is information on
18 when a drug that's in shortage will be available.
19 There was the question about what has
20 changed, and that's answer I think a lot of us would
21 like to have. Why all of a sudden has it peaked like
22 this? What's going on? We have speculated on the

1 reasons at a lot of different meetings. But what's
2 really happening? Who's investigating? Is the GAO
3 going to be coming up with answers for example? Where
4 do that sit? That would help everybody I think to know
5 what is going on here.
6 Guidelines for alternative therapies. I
7 hadn't heard that before. Is that doable? I don't
8 know. And I've heard this before too, the concept of
9 stockpiling, having emergency supplies. I thought I
10 heard Dr. Lichtenfeld -- tell me if I'm wrong -- but
11 did you not say something about maybe NCI having a
12 group of drugs that would be available for short-term
13 use in emergency or manufactured for short-term uses in
14 emergencies?
15 DR. LICHTENFELD: Well, I mentioned that that
16 is one opportunity or one option to explore. I'm not
17 sure that's the solution. Someone else mentioned the
18 possibility of stockpiling.
19 MR. COHEN: Right.
20 DR. LICHTENFELD: That was another presenter.
21 MR. COHEN: Okay. Doing something about
22 price gouging I heard. I don't know that FDA can do

1 something directly about that, but it is something we
2 want them to hear.
3 Fair and equitable distribution. That is a
4 concern for all of us. How is it at that the gray
5 market dealers have these drugs and we can't get them
6 through our normal suppliers? And is there a way to
7 have some fair distribution system?
8 I heard from VA Federal waivers for Federal
9 agencies to be able to take advantage of acquiring it
10 from foreign sources.
11 What are the top three though in your
12 opinion? Can we have some discourse on that from the
13 group? Would somebody like to speak? Yes.
14 DR. BERRY: Yes. I think that the first that
15 you mentioned is actually very critical, and that is
16 knowledge as soon as possible regarding the scope and
17 the duration of shortages. And this would allow
18 practitioners to plan for the shortages and to seek
19 alternative drugs for use. So there are two parts of
20 that, both the scope, how short will this be, and the
21 duration, so that we can ration drugs or utilize them
22 in ways that are most effective in prolonging the

1 supplies that we have.
2 MR. COHEN: Thank you, Dr. Berry. Dr. Blum.
3 DR. BLUM: Of the things mentioned, I can
4 tell you from the emergency physician's standpoint
5 advanced notification really doesn't help me very much.
6 I need what I need when I need it. And it's often very
7 hard to predict; because of the breadth of the kind of
8 patient problems we see in the emergency department,
9 you often don't know what you need until that
10 particular occasion arises, and then you find out that
11 the drug you need is in short supply.
12 The other thing that's very frustrating for
13 us is that this seems to be a hyperdynamic sort of
14 situation. Literally, we'll have the drug one day, we
15 won't have it the next, then we won't have it. It's
16 virtually impossible to plan for.
17 The idea that I heard that makes the most
18 sense for at least the emergency drugs that we need is
19 some sort of stockpile. But again, you need to be able
20 to stock the stockpile at some point. Somebody needs
21 to make these drugs, and pharmaceutical representative
22 spend bazillion of dollars trying to influence me to

1 buy their drug. On most of these drugs, I'm sold. I'll
2 buy them. I'll use them. Just make them.
3 (Laughter)
4 DR. BLUM: Just make them. But I have to
5 believe because they're not making them there some sort
6 of barrier there that we have to tear down. I don't
7 know if it's a regulatory barrier. I don't know what
8 it is, but I could tell you everybody worries about
9 safety of drugs, and that's important. I don't want to
10 diminish it, but I can tell you, it's really unsafe not
11 to have a drug. That's pretty unsafe too. I'm sorry
12 I...
13 MR. COHEN: Thank you. Yes, ma'am. Would
14 you give us your name and affiliation? I can't see.
15 MS. PHAM: I am Kathy Pham. I am the
16 representative for the Pediatric Pharmacy Advocacy
17 Group. I didn't speak earlier because we didn't have
18 anything formal prepared, but I think it's important
19 for us to add on to Dr. Pursley's sentiments and how it
20 impacts pediatric pharmacy.
21 We would definitely advocate for information
22 probably trying to look at from three categories

1 because ultimately, yes, we agree we'd really love to
2 have the drug, and that's first and foremost our
3 priority. But when you don't, what is next?
4 And so information to the healthcare
5 providers that we can share so that we can maybe
6 minimize some of the frustrations directed at pharmacy
7 because we are the middle man. We're the one saying
8 "Sorry, we don't have it."
9 Also information to the parent. Another
10 great initiative through PPAG is trying to be advocates
11 to the parents and the patients as well. Sometimes
12 they deserve just as much if not more education on why
13 this is all happening, but maybe provided in a way that
14 the much more user friendly to their level of
15 understanding versus the licensed independent
16 practitioner's perspective.
17 So those two categories of audiences and the
18 information that the update can provide so we can
19 actually advocate to these parties and give that
20 information instead of constantly having to explain and
21 we're not actually sure our explanation is really
22 accurate, so a lot us is educated guessing from what

1 we've read in the media.
2 So having that direct communication from the
3 FDA to be able to provide to these people probably also
4 increase the confidence in the FDA in terms of what
5 they're doing and what they're trying to show in
6 transparency as well.
7 The last thing is information amongst the
8 organizations and practitioners in terms of what
9 they're doing. So when you don't have that drug, in
10 pediatrics the only way we can get around it -- because
11 we don't have guidelines; we'd love guidelines, but
12 they don't exists; a lot of things in literature don't
13 exists -- is what are you doing about it? We have
14 listserv particularly in our group, but I know that
15 other professional societies have pediatric subgroup
16 like ASHP and ACCP, but we just have to get their own
17 email listserv and say, "So I ran out of calcium
18 gluconate today. What are you doing?" And literally
19 that is all we have to go on is the community of
20 practitioners and what their solution is.
21 So even if the FDA would like to collaborate
22 to some of these stakeholder groups and maybe pool

1 their responses and their solutions of alternatives
2 that they've used and maybe publish that on their Web
3 site at well; because what we're concerned about as a
4 society is -- I am also the neonatal clinical pharmacy
5 specialist at Children's National Medical Center. When
6 my NICKU (ph) calls upon me to help with a solution, I
7 actually use that as a great opportunity for
8 professional collaboration with our LIPs to say, "Okay,
9 Dr. So-And-So, let's talk about this and what can we
10 do."
11 So although the frustration is directed at
12 pharmacy can be vast, the silver lining to this cloud
13 is that's a great opportunity for collaboration amongst
14 physicians, nurses, and pharmacy to be able to come up
15 with a solution together.
16 So if we can come up with solutions, it would
17 be great to have a shared pool of those solutions to
18 share with places that are not like Children's National
19 who do not have a pediatric pharmacy subspecialist in
20 every single area. Maybe especially even the hospitals
21 that have no clinical subspecialist in pharmacy.
22 Like for instance, we have fellows that go to

1 George Washington University, and one minute we're
2 telling them we have one vial left of this, and they go
3 to GW, and they have none. And so there's an
4 inconsistency in why, and they don't have any
5 pediatrics, just the NICKU, and now they're NICKU
6 within the adult world.
7 So those are the areas that are most
8 concerning to us as a society.
9 MR. COHEN: Thank you very much. Dr. -- Ali
10 McBride.
11 MR. MCBRIDE: Thanks, Mike. I appreciate it.
12 MR. COHEN: Sure.
13 MR. MCBRIDE: I really think there are
14 several points you made that have really focused on the
15 issue. What's the best recommendation? I can't beat
16 Dr.
17 Blum's on this: Just give me drug. I think
18 that's the most important part, so I really can't
19 follow up on that.
20 But we do have -- HOPA members have been of
21 concern because we have two issues. The first issue is
22 that there is not a fair and equitable distribution of

1 drug across the country. We have local, regional
2 variances between drug therapies. And you just heard
3 before one person has a vial another person has zero.
4 But from our center and standpoint, when you go to the
5 larger medical centers, to a localized area for an
6 infusion center for a smaller community hospital, as
7 what was shown before, these areas may not have the
8 buying or purchasing power to obtain the correct drug
9 or the needed drug based on the situation. And what's
10 happening is we are seeing at filter-down effect in
11 which smaller hospitals, smaller infusion centers are
12 not able to actually provide drug to their patients and
13 therefore is distributing down to larger medical
14 centers, which is therefore then depleting those
15 centers' drug supply, which may have an increased
16 amount of supply available. And that's been a big
17 issue as we're redistributing our patient population
18 from the smaller sites to a larger medical center
19 therefore decreasing the drug supply we have and
20 therefore increasing a drug shortage just in that
21 medication.
22 And the second issue is strictly in oncology

1 that we're hearing in the recommendations. So far
2 there is only very little recommendations provided for
3 drug therapies on drug shortages. So what happens when
4 doxil goes offline? What happens when thiotepa goes
5 offline? What happens when danuorubicin goes offline?
6 What is the evidence for that? And where is it
7 provided? A lot of times there is not much information
8 on that, and sometimes it's up to the physician, the
9 pharmacist, the nursing group, the healthcare
10 professionals to work on that together. And
11 unfortunately, we don't have that information provided
12 in a lot of detail.
13 MR. COHEN: Thank you. Dr. Lichtenfeld.
14 DR. LICHTENFELD: I appreciate all the
15 comments that everyone has made, and I'm pretty sure
16 all of the comments have been made about information
17 and understanding where the drug is, where the drug
18 isn't, and when do we have it, when we don't have, and
19 so forth. But I haven't heard anybody say why are we
20 here in the first place.
21 I would be remiss if I did not say that there
22 is a substantial amount of concern in a number of the

1 professional and patient communities as to why we're
2 here. And unfortunately, it has to do with money, and
3 we need to have an understanding -- I mentioned in my
4 testimony; other have alluded -- we need to quickly
5 bring together the appropriate parties. We need to
6 quickly understand what's going on here, and we need to
7 quickly address it.
8 I'm going to say what I said before: I find
9 it hard to believe that in this country that because it
10 doesn't make a lot of money we can't provide necessary
11 drugs and vitamins and electrolytes for our patients.
12 That is frankly from my -- I won't use the word I'm
13 going too. I have to be careful. I'm on TV with a lot
14 of people --
15 (Laughter)
16 DR. LICHTENFELD: -- it's terribly, terribly
17 unfortunate we've gotten to that point. These are not
18 complex drugs. These are no biologics. These are
19 drugs that have been around for 40 years and probably
20 some kids out the kids out there with a chemistry set
21 who might be able to make these drugs. That we are out
22 of supply of cytarabine, which is a drug used in

1 leukemia, were St. Jude and the Children's Oncology
2 Group is suspending curative treatment for children in
3 this country is a national dilemma, disaster, and it's
4 shameful.
5 So let's talk about root cause. Let's talk
6 about pointing the fingers, doing what we need to get
7 it fixed. There are solutions out there that have been
8 suggested, whether it be public-private partnerships,
9 whether it be Government intervention, which many of us
10 would not prefer; but if that's a solution, let's get
11 to it, and let's talk about solutions. We shouldn't
12 have information about when the drug is coming back. We
13 shouldn't have to worry about the problem in the first
14 place.
15 MR. COHEN: Thank you very much, Dr.
16 Lichtenfeld. We have time for one more comment. Dr.
17 Pursley.
18 DR. PURSLEY: I think we're asking or
19 expecting FDA to do some things that they haven't done
20 traditionally that they haven't been expected to do
21 these things and certainly haven't been funded to do
22 these things. And I worry a little bit that looking at

1 some of the individual issues we're sort of thinking
2 incrementally when we might need -- I hesitate to use
3 this adjective but -- a radical restructuring of the
4 way we're set up. I know a lot about silos. I'm in an
5 academic medical center, but I certainly understand
6 that there are limitations to working within your silo,
7 and it seems like there is a lot of opportunity for
8 partnership here.
9 I worry about the three-yards-and-a-cloud-of-
10 dust approach and think that we need to throw the ball
11 down the field a little bit. So taking examples of --
12 unlabeled drugs, that's a reality for pediatrics; but
13 through this partnership with FDA, pediatricians have
14 made a lot of strides in addressing this issue for
15 kids, but there are still a lot of unlabeled drugs out
16 there that need to be monitored. I think that's an
17 important thing.
18 Stockpiling. It seems like that's something
19 that has been utilized by the CDC effectively, and
20 maybe there's some lessons to be learned from there.
21 And there's I'm sure multiple other opportunities to
22 radically look at how we're addressing this issue.

1 MR. COHEN: Okay. I do to make time for one
2 more comment. So would you go ahead please. And
3 that's it.
4 MS. DAVENPORT-ENNIS: What I'd like to do is
5 follow up on that comment so simply say I do believe
6 that the FDA is going to need some support from other
7 Federal agencies. I think it's the third time on
8 record I've said this. I think we need to answer the
9 question what is the role of the DEA, what is the role
10 of the FTC as we move forward in trying to find
11 solutions.
12 And I would like to express that, again, the
13 National Patient Advocate Foundation is in fully
14 support of the proposals that are being made before
15 this panel today on behalf of the patients that we
16 represent. Thank you.
17 MR. COHEN: Thank you to everyone on the
18 panel. Great job. Great ideas. Now it's question and
19 comment period.
20 DR. COX: Okay. Thank you all, panelists.
21 Now we'll move to the question and comment period, and
22 Dr. Rufkin was the first. Yes, that's it. That's

1 fine. Yes. And Dr. Rifkin, if you'll further
2 introduce yourself.
3 DR. RIFKIN: Well, thank you very much. I'd
4 like to thank the FDA for convening a very timely
5 workshop. I'm Dr. Robert Rifkin. I'm a community
6 oncologist whose sphincter is less tight than my
7 emergency tight than my emergency colleague.
8 (Laughter)
9 DR. RIFKIN: But in any event, I'm also on
10 the U.S. Oncology Research Committee for Hematology and
11 a member of McKesson Specialty Health. And my last
12 job, unfortunately, is I chair the pharmacy and
13 therapeutics committee at our local hospital.
14 With that in mind, I think that this actually
15 is a relatively new issue. We didn't deal with this 10
16 or 12 years ago. We always got everything we wanted.
17 And I'm reminded of the last patient I saw, who was
18 unfortunately a physician's wife who's an attorney who
19 developed colon cancer. She needed a resection. There
20 was no propofol. There was no succinylcholine.
21 She survived that, and then she needs
22 adjuvant therapy with the FOLFOX regimen, and you saw

1 that every drug that's shorten is on that list. And
2 then when we went to go off label, the payer denied
3 reimbursement. And I think that single case sums up the
4 biggest problem that we have.
5 We look it from the community standpoint, and
6 clearly the system is broken. And whether radical
7 restructuring is the fix or not, we see things as
8 physicians. We go look at the Web site, and the
9 commonest cause for a drug shortage is increased
10 demand. What on earth does that mean? Colon cancer
11 hasn't all of a sudden tripled. Why are we running out
12 of 5-FU? Why are we running out of leucovorin?
13 And I think we have a unique opportunity in
14 this room because all of the stakeholders are present.
15 We need an unprecedented collaboration between not only
16 the FDA, professional organizations. I pay due to half
17 the people that are sitting over there, and I think
18 we're getting our money's worth, but we really need to
19 bring industry into the picture.
20 And I think quite honestly everybody's danced
21 around it: It's a money issue. Why would I make
22 propofol for 48 cents for a 20 cc vial? We need to

1 restructure things so we can have an effective price
2 structure and so that we can do exactly what my
3 emergency room colleague said, and that's if you need
4 the drug, you should be able to get it. You should be
5 able to use it.
6 The vast majorities are old things. The last
7 one I faced as the PNT committee chair was the cysteine
8 shortage. Cysteine goes in neonatal TPN. It decreased
9 the amount of calcium and phosphate you need to make
10 bones, and we have neonatal patients that we can't give
11 enough nutrition to to grow and develop shortly and
12 normally.
13 So with that in mind, I think I would take
14 this opportunity as one of Nancy's board members as
15 well to really urge all of the stakeholders in the room
16 to come together and collaborate and break down the
17 financial barrier. This isn't one like the national
18 debt. I think we can actually get in the same room and
19 talk about it. Thank you very much.
20 DR. COX: Thank you, Dr. Rifkin. And now our
21 next speaker is Mr. Bult. If you're in the room, come
22 join us. And similarly, if you'll introduce yourself

1 further, that'll be much appreciated. Thank you.
2 MR. BULT: Good morning. My name is Jan
3 Bult. I'm the president and the CEO of the Plasma
4 Protein Therapeutics Association. This association is
5 the international trade one for the world's major
6 producers of plasma derived and recombinant analog
7 therapies. Its North American data program was
8 developed in response to a shortage of intravenous
9 immunoglobulins in the late '90s. Many IV users are
10 dependent on regular infusion of the therapy and demand
11 that information of the scope, likely duration, and
12 causes of the shortage. The shortage was also the
13 subject of congressional hearings and substantial media
14 attention.
15 To address this situation as well as future
16 supply issues, the HHS Advisory Committee of Blood
17 Safety and Availability made specific recommendations
18 regarding an industry-wide supply data program to FDA.
19 The key elements are that the industry trade
20 associations should be directly involved; that the
21 program should involve collection and dissemination of
22 standardized information; that the information reported

1 should be quite detailed; and the data should be
2 reported on a monthly basis.
3 By the spring of 1998, FDA, PPTA, and
4 manufacturers of the therapies including members and
5 nonmembers had all complied with this recommendation.
6 The data program provides monthly aggregate
7 information on the supply of immunoglobulins, albumins,
8 and hemophilia clotting factors. This information is
9 reported directly to manufacturers that contribute the
10 data to FDA and HHS. The information is also reported
11 publicly on its Web site.
12 Anti-trust compliance has been a priority
13 since the program's inception, and it incorporates many
14 competitive safeguards. One is the use of an
15 independent third-party vendor to collect the
16 individual company data. As a result of this firewall,
17 individual company data is not made available to the
18 association or to any manufacturer of these therapies.
19 Both PPTA and the manufacturers only receive the
20 aggregate industry-wide data.
21 Providing the data only to regulators and
22 industry is not enough. Patients also require access

1 to the data. The PPTA program empowers patients and
2 physicians to make better informed decisions regarding
3 the treatment. The supply of timely data has proven to
4 be very helpful in times of real shortage.
5 Another benefit is that the data can be very
6 helpful when there are rumors about shortage. We've
7 seen this several times and were able to provide
8 factual data and eliminate any potential concern.
9 One example in which the data were most
10 helpful at separating true product shortage from supply
11 disruption occurred in 2005 and 2006 when changes in
12 the Federal reimbursement schedule resulted in shift
13 inside of service and results in patient access issues.
14 The system helped sort out the true cause of the access
15 difficulties.
16 One thing that we have learned is that the
17 industry must make a sustained commitment to supply
18 data reporting, implementing a reporting system only
19 when there is a perceived shortage and discontinuing
20 when it appears supply will not work.
21 As a final note, collecting, aggregating, and
22 reporting supply data takes time and expertise; in

1 other words, it cost money. A data program must also
2 be run in an anti-trust compliant manner, which
3 requires ongoing legal input and imposes other layers
4 of expense. As we all know, FDA is already operating
5 under substantial resource constraint and is not in a
6 position to man a shortage-related early warning system
7 for the multitude of drug products it currently
8 oversees. The PPTA data program is an example of
9 industry stepping up to lighten this burden. Thank you
10 for attention.
11 DR. COX: Thank you. Now we'd like to invite
12 Marc Stewart to the podium. You have three minutes.
13 DR. STEWART: Thank you very much. I'm Marc
14 Stewart. I'm a hematologist/oncologist and medical
15 director in Seattle at the Fred Hutchinson Cancer
16 Research Center and University of Washington. I also
17 chair the scientific board of directors of the National
18 Patient Advocate Foundation, which includes other
19 members such as Johns Hopkins, Mayo Clinic, and
20 Northwestern University.
21 As you've heard today, many of the physicians
22 are struggling to provide care for cancer patients with

1 many different diagnoses. At my institution, over the
2 past six months we've experienced drug shortages in at
3 least 15 different drug categories used to treat
4 patients with cancer. Many of these are key drugs for
5 which substitution, as you've heard, can lead to
6 diminished survival or increased toxicity.
7 And since most of the centers that I
8 represent are academic centers, the impact on research
9 trials and translational research has been quite
10 substantial. About 5 to 10 percent of our trials are
11 affected directly, and the potential effects here could
12 be as high as 20 to 30 percent if the accumulated
13 shortages continue.
14 Just a couple of example of the challenges we
15 face. I receive numerous calls from other centers
16 asking our hospital to supply these drugs in short
17 supply. Some of the most frequent calls come from
18 Alaska Native American hospital in Anchorage, Alaska,
19 where an outstanding solo oncologist is struggling to
20 provide Native Americans at a center with the best care
21 possible. She treated recently a young patient with
22 lymphoma, and although the shortage issue was resolved,

1 initially she asked two questions when presented with
2 the shortage dilemma. One is why am I at risk for not
3 achieving a complete cure rate as I would if I got the
4 standard drugs? And second, if I have to go elsewhere
5 to get these drugs how can I possibly afford to travel
6 to places like Seattle and bring my three children
7 along with me, a substantial financial challenge?
8 The final example relates to an upfront
9 clinical research study that we have from multiple
10 myeloma. It includes the drug doxil, which you heard
11 is in short supply. A 40-year-old fellow with multiple
12 myeloma was offered enrollment on this trial. He
13 received the first cycle of the drug before abruptly
14 our doxil supply diminished to the point where we could
15 not complete the additional three cycles of this drug
16 regimen. He ultimately was transferred to another
17 facility where he did complete the regimen, but he
18 asked two questions. One was why do I have to change
19 physician, why do I have to change nurses, why do I
20 have to change the facility that I'm in? And then the
21 second question is why in the world would I ever
22 participate in a research study again?

1 So, finally, I think it's important to note
2 and applaud the progress that the FDA has made in
3 diminishing the shortages. And we would of course
4 continue to encourage them to reduce further
5 impediments. I like Dr. Rifkin's summary where it's
6 really going to take kind of a board interaction with
7 multiple agencies and multiple organizations in order
8 to achieve success here.
9 It is interested that at least in our
10 experience generic drugs far outweigh the brand names
11 in terms of the ratio of those in short supply, and
12 that can't help but lead me think about the money issue
13 again, and we need to understand that a little better.
14 So in summary, our patients deserve access to
15 the best and most established drugs available to
16 continue to live as long as possible and with the best
17 quality of life we can provide. Thank you.
18 DR. COX: And Russell Shipley. Three
19 minutes.
20 MR. SHIPLEY: Good morning. We're getting
21 close to the lunch hour. I have a very brief statement
22 I'd like to present. My name is Russell Shipley. I'm

1 on the senior staff of CHADD, Children and Adults with
2 Attention-Deficit/Hyperactivity Disorder, a national
3 nonprofit organization that improves the lives of
4 people affected by ADHD. CHADD truly appreciates this
5 opportunity to comment at this public workshop.
6 CHADD is very concerned about reports of
7 shortages of medications that treat ADHD. CHADD wants
8 to encourage effective collaboration by DEA with
9 manufacturers to avoid shortages of active ingredients
10 needed to complete the manufacture and distribution of
11 drugs with controlled substance used to treat Attention
12 Deficit and Hyperactivity Disorder. These shortages
13 are a real concern to patients and families affected by
14 ADHD. It causes delays in getting their prescriptions
15 filled at the pharmacies. CHADD encourages a more
16 efficient process by FDA and DEA to prevent these
17 chronic shortages. Thank you very much.
18 DR. COX: Thank you. I'd like to invite C.
19 Allen Black to the podium, and please state your
20 affiliation further and introduce yourself further.
21 Thank you. Three minutes.
22 MR. BLACK: Thank you very much. My name is

1 Dr. Allen Black. I have a Ph.D. in immunology. I'm
2 also an attorney. I teach the biotechnology law class
3 at the University of Pittsburgh. But most importantly,
4 I represent over 50 patients suing Genzyme and Mt.
5 Sinai Hospital for causing and failing to mitigate a
6 drug shortage that has been going on for now three
7 years.
8 Fabry disease is a genetic disorder; you're
9 born with it. Patients used to die by the time they
10 were in there 40's, but there was an invention called
11 Fabrazyme that was paid for by U.S. tax dollars, NIH
12 grant money, that allowed patients to finally be
13 treated and live normal lives. One of my close friends
14 is on treatment.
15 Fabrazyme of course is patented. Mt. Sinai
16 licenses this patent to Genzyme Corporation
17 exclusively. However, as supplies went down due to a
18 contamination problem -- in fact the FDA is currently
19 investigating under a consent decree -- Genzyme decided
20 to ship full dose Fabrazyme overseas to European
21 patients while denying American citizens access to full
22 FDA-approved doses. In fact if you're diagnosed after

1 June of 2009 and you're an American, you receive no
2 treatment whatsoever.
3 My clients they came to me. They said,
4 "Allen, you work in this area. What are we going to
5 do?" Well, the first thing that we did is we
6 petitioned the NIH. The obvious problem here is
7 there's no competitor. So if one manufacturer can't
8 make the drug and has a monopoly, obviously a second
9 manufacturer coming into the market should help
10 mitigate the problem. However, of this date, we have
11 not heard anything back from the NIH other than a
12 tentative disapproval in December that's currently
13 being reheard.
14 We have also petitioned the FDA to prevent
15 the drug from being sent overseas. Now it's not like
16 overseas patients don't have access to a treatment.
17 They have access to an alternative drug called
18 Replagal. So in addition to having access to full-dose
19 treatments, they have alternative to an alternative
20 drug which is not FDA approved.
21 As a final note, we cannot let private
22 companies dictate where drug is allocated and to whom.

1 That choice should be with the doctors and the FDA and
2 the Government. We must create rational allocation
3 systems when there is a shortage. And finally, we must
4 prevent, at least in my view, the first preferential
5 deletion of Fabrazyme patients from the U.S. as opposed
6 to other genetic subpopulations. Thank you very much.
7 DR. COX: Thank you. Our next speaker is
8 Kathy Pham.
9 MS. PHAM: I spoke earlier, but this is
10 actually as a response to a previous question earlier
11 this morning about the gray market that I think Dr. Fox
12 had a limited response due to her institution's not
13 being able to use it.
14 I think being on camera nobody wants to
15 incriminate their own institution for use of this
16 particular resource, but I would say more generically
17 that those institutions that serve a special
18 population, like pediatrics, where a limited supply
19 from the gray market could be all that they need just
20 to at least be able to say they have something on their
21 shelf, there are things that may not being used as
22 often as in the adult population, but when you need it,

1 you need it. So it's more likely that the gray market
2 may be utilized for these smaller institutions or
3 populations that have less frequent use.
4 The problem is, going back to the
5 distribution, is that then one hospital may have been
6 able to acquire such products; and then the same
7 practitioner goes somewhere else, and they're being
8 told that they can't get it. Well, then how come the
9 other hospital is able to get it. So that
10 inconsistency and where that supply comes from does
11 cause for some issues clinically.
12 The other thing is that price gouging there
13 is absolutely insane. It's probably breaking a lot of
14 hospital budgets because something like Lasix should be
15 20 cents, and can be charged $20 a vial. So there is
16 significant price gouging there. Your best resource to
17 find out where this is all coming from is probably the
18 network of pharmacy buyers. I know there are listservs
19 among the buyers that keep in communication when
20 shortages affect them. The problem is because there is
21 probably some questionable concerns about where these
22 are coming from and under what storage condition I

1 don't know that anyone is going to voluntarily tell you
2 about their gray market resources or how to contact
3 those people. The other thing is that they are
4 probably concerned that if they call out a gray market
5 resource that that would be one less lifeline for
6 getting their supply.
7 So those are probably limitations of trying
8 to figure out where the gray market is coming from.
9 DR. COX: Thank you. And our next speaker,
10 Joel Zivot. You have three minutes. And please
11 introduce yourself further when you get to the podium.
12 DR. ZIVOT: My name is Joel Zivot. I'm an
13 anesthesiologist and critical care medical specialist.
14 I work at Emory University Hospital in Atlanta,
15 Georgia, and I'm also a member of the American Society
16 of Anesthesiology. I sit on the committee on ethics
17 for that society. And I wanted to address the problem
18 of off-label use and responsible stewardship by those
19 of us that prescribe.
20 I sit on the P&T committee of my hospital,
21 and we have a discussion on heart guardrails that could
22 be used on smart infusion pumps. For that's of you not

1 familiar with this, it's a device that infused
2 medication at a continuous rate, and you can actually
3 program it to prevent you from exceeding certain kinds
4 of doses that you set. Now in spite of a lack of a
5 label indication with respect to increasing dosages or
6 even a lack of clinical literature to support practice,
7 we as a group are unable to agree on placing heart
8 guardrails.
9 In desperate circumstance, I understand the
10 desire to do something. I've been there myself many
11 times, but this practice collides with the fundamental
12 medical ethical principle of distributive justice when
13 supplies are short.
14 We need to develop a system of drug
15 utilization that is ethical and assumes an ongoing
16 shortage while we work in the issue of increasing
17 supply. Thank you.
18 DR. COX: Thank you.
19 DR. KWEDER: Before we break for lunch, for
20 those of you who weren't here, I'm Sandra Kweder. I'm
21 the Deputy Director of CDER's Office of New Drugs.
22 We've heard a lot comments, and we so appreciate you

1 being here this morning, all of you, really all of you.
2 Your comments were on target and very thought
3 provoking. We are all in this together.
4 I just wanted to circle back to Dr. Cox's
5 presentation because some of the comments, particularly
6 yours Dr. Blum reminded me of this, and yours also: Why
7 are we here in the first place? Ten years ago, we
8 weren't here. So what is it that has changed?
9 And just a little historic relevance. The
10 Drug Shortage staff that we have today was started in
11 1999 because we were worried about Y2K and what would
12 happen at the turn of the century when manufacturing
13 systems that were reliant on time, automated systems
14 were reliant time and date changes in automated
15 programs would they be able to continue operations. We
16 were seriously concerned and spent a lot of time
17 working with the industry to prepare to assure that
18 production would not be affected by Y2K. Wonderfully,
19 it wasn't, and there were no problems.
20 But as the staff was in place and had been
21 working on this, we started to hear trickles of
22 information about drug shortages or potential

1 shortages. But we don't think that the reason that
2 there are more today really has anything to do with the
3 fact that people are reporting them. We think that
4 they're real. You all know they're real. They didn't
5 exist -- this didn't happened very often 20 years ago.
6 And so I would like to just for thinking
7 about this and how to address this, what are the root
8 causes. And some people have mentioned financial
9 pressures and incentives. There is a Department of
10 Health and Human Services working group that's
11 beginning to look at some of that.
12 I would take you back to Dr. Cox's
13 presentation, which you have in free form, it's not in
14 the book, to slides 8 and 9 -- and I don't want you to
15 necessarily put them up -- but when we look at what our
16 trends have been, in 2010, 54 percent of the shortages
17 and potential shortages were related to product quality
18 and significant manufacturing problems; 21 percent were
19 due to delays and capacity issues where there wasn't
20 necessarily a crucial problem.
21 The product quality things. These aren't
22 like minor things where dotting I's and crossing T's.

1 These are particulate matter, fungus, endotoxins, metal
2 shavings in products.
3 The delays are due to companies trying to
4 avoid development of those things with routine
5 maintenance kinds of things where they need a part,
6 they need to shut down temporarily. But the margin in
7 the market is so tight that any interruption trickles
8 down into a shortage.
9 Someone mentioned increase in demand due to
10 another shortage. Actually, that only made up about 4
11 percent of the ones that we were tracking. And we
12 recognize that our data and the ASHP's are maybe a
13 little bit different.
14 If you go back to Dr. Cox's slide number 9 on
15 the older, sterile injectables, one thing that's in the
16 middle of the slide that's really important is that
17 seven manufacturers make up large percentage of this
18 market, seven. Many of those manufacturers also work
19 under contract for the original holders of the NDA to
20 make their product as well. So some of the shortages
21 that have been mentioned today where there are multiple
22 drugs in a series, sometimes those shortages are all

1 related to a single manufacturer that makes dozens of
2 products. So just to try and fill in the blanks.
3 And again, we work really hard, and a lot of
4 what our Drug Shortage staff do is really outside the
5 boundaries of what FDA has ever been asked to do. We
6 work between companies; we try and talk to them, and
7 it's unheard of 10 years ago for Val Jensen to call up
8 a company and say, "Hey, listen, could you ramp up your
9 -- how long would it take you if you had to to ramp up
10 your production of product Z?" "Well, I can't tell you
11 why, but we're concerned that there may not be enough
12 on the market in the next six months. You think you
13 could ramp it up, okay? Because I can't tell you that
14 your competitor has got a big problem." But everyone
15 has sort of learned the code, and the industry has
16 really stepped up to the plate to try and mitigate
17 these.
18 But again, our goal is to stop this. The
19 less that FDA has to do, the better as far as we're
20 concerned in this area; because as was all are, we have
21 other work to tend to. This is extraordinarily
22 important, but it should be able to be prevented. We

1 should be able to make these products that the medical
2 community and patients rely on.
3 So with that, we're going to dismiss for
4 lunch. Do you have suggestions for folks about where
5 they can go?
6 DR. COX: There should be lunch carts
7 outside, and others may want to venture off campus too.
8 We had a considerable number of folks here and a
9 limited period of time. We will start back at I'll say
10 1:05. We'll start back at 1:05. Thank you all, and I
11 want to thank all the speakers and panelists from this
12 morning's panel. Thank you.
13 (Off the record)
14 (On the record)
15 DR. COX: Welcome back after lunch, and we
16 appreciate everybody making it back in such a timely
17 fashion, and we'll start the afternoon session. And
18 our first speaker is Joseph Hill, the American Society
19 of Health-Systems Pharmacist, and he'll be providing a
20 legislative update. So, Joe, I'd like to invite you to
21 the podium. And you're welcome to do it too from your
22 seated position if you'd prefer.

1 MR. HILL: Great. Thank you. Makes it
2 easier because I only have about five minute. Good
3 afternoon, everyone. I just wanted to give you all a
4 brief update on legislative efforts for a lot of good
5 ideas and a lot of work with FDA.
6 There are currently two bills in Congress,
7 one in the House, one in the Senate, the Preserving
8 Access to Life-Saving Medications Act. The Senate bill
9 is Senate Bill 296 sponsored by Senator Amy Klobuchar
10 of Minnesota and Senator Bob Casey of Pennsylvania. On
11 the House side, we have HR2245 sponsored by
12 Congresswoman Diana DeGette of Colorado and Congressman
13 Tom Rooney of Florida. The legislation really gets at
14 one of the issues that was mentioned in a presentation
15 this morning of requiring manufacturers to provide
16 early warning when they experience a production
17 interruption as soon as practicable for a production
18 interruption or in the case of a product
19 discontinuation up to six months in advance.
20 Up until now, we had been using the numbers
21 from FDA that the agency was able to avoid 35 shortages
22 in 2010 when they had access to this information. But

1 this new information on the number of -- 99 of them
2 this year -- I think certainly it helps really make the
3 case that while we recognize that it is not a complete
4 solution, that it does not prevent shortages from
5 occurring, but it would be extremely helpful to the
6 agency, and frankly it's is something that we can do
7 right now.
8 So as look toward some of these other
9 solutions that will be discussed this afternoon, some
10 of them more complex than others, I think that these
11 bill really do represent that critical first step, and
12 we are very thankful for the members of Congress that
13 took the leadership on this issue.
14 And just to also, in case you didn't know,
15 the House Energy and Commerce Health Subcommittee held
16 a hearing on Friday just to examine drug shortages, and
17 they had a wide array of folks testifying. It was a
18 very good hearing, a very productive hearing, very
19 bipartisan in nature, so I think the pieces are
20 together. People are working collaboratively toward
21 solution, and we're certainly supportive of these bills
22 although we recognize that much more can be done. Thank

1 you.

2 DR. COX: Thanks, Joe. And now our next

3 presentation is on recommendation from the co-conveners

4 to the stakeholders work group of the Drug Shortages

5 Summit. And just so folks know, in the agenda the back

6 page it list the participants in the work group

7 activity, so you'll have that there for your reference,

8 and presenting will be Jason Byrd from the American

9 Society of Anesthesiologists and also Juliana Reed for

10 Hospira. So welcome.

11 MR. BYRD: Thank you. And thanks to the FDA

12 for convening this workshop to address drug shortages

13 and the opportunity to present before you. I'm Jason

14 Byrd, Director of Practice Management, Quality and

15 Regulatory Affairs for American Society of

16 Anesthesiologists. And today I along with my colleague

17 Julie Reed have the privilege of briefly presenting

18 some of the efforts that stakeholders, many of whom are

19 in this room representing the entire healthcare

20 delivery system, have undertaken to address the

21 national drug shortage problem.

22 The focus of our presentation is on consensus

1 issues identified by these stakeholders along with
2 draft proposals to potentially address, mediate, and or
3 resolve such issues.
4 I have no financial conflict though I remind
5 everyone I work for ASA. Julie Reed also has no
6 financial conflicts, and she is employed by Hospira.
7 As a result of the many stories, issues, and
8 concerns so well articulated by this morning's
9 speakers, a number of organizations decided to convene
10 a multi-stakeholders drug shortages meeting in November
11 2010. Those co-convening organizations driving that
12 effort were the American Hospital Association, American
13 Society of Anesthesiologists, American Society of
14 Clinical Oncology, American Society of Health-System
15 Pharmacists, and the Institute for Safe Medication
16 Practices. The purposes of the November 2010 Summit
17 were to discuss the breadth and scope of drug
18 shortages, identify causes, and develop proposals need
19 to address such shortages.
20 While a good amount of progress was made that
21 day, all stakeholders recognize that just as Rome was
22 not built in a day additional conversations and work

1 would need to occur to meet our collective goals. Thus,
2 the stakeholders divided issues identified during the
3 Summit into multiple work groups to continue the work.
4 Julie and I are focusing our discussion on the
5 legislative and regulatory work group efforts.
6 As you can see, this work group met multiple
7 times over the last year including two in-person
8 meetings in Washington, D.C. It's also important to
9 acknowledge that the issues and draft proposals
10 identified today represent our current collective
11 thought but will likely require modification or
12 additional specification over time. And while the
13 recommendations presented represent the general
14 consensus of the work group, they do not necessarily
15 reflect the formal policy approval of any specific
16 participating organization.
17 In addition to the co-convener organization
18 listed on the previous slide, this slide represents the
19 collection of organizations that have participated in
20 the effort to address drug shortages through the Summit
21 and/or the work group deliberations. We believe the
22 significant number of participants demonstrates the

1 enormous complexity of drug shortages as well as the
2 commitment of those same participants to find workable
3 solutions.
4 We would be remiss not to also identify the
5 advisory role played by the FDA, CDC, and NIH during
6 last fall Summit and as questions have arisen over the
7 past year with regard to the process and authority of
8 the Federal Government. With that introduction, let's
9 turn our attention to the issues and proposed
10 solutions.
11 Through our discussions, one issue that
12 continuously surfaced with broad implication was the
13 stakeholders' perception that there are currently
14 insufficient Federal resources allocated to the
15 regulatory management of rapidly escalating drug
16 shortages.
17 For example, there are currently, as
18 identified earlier today, four staffers working within
19 FDA's Drug Shortage Program handling shortages for the
20 entire country. While those staffers are very
21 dedicated and work very hard, as we have seen today,
22 new shortages continue to increase at a record pace and

1 add to FDA's significant burden.
2 In addition, the new generic drug user fees
3 and updates to the prescription drug user fees next
4 year are an ongoing sign of support our industry
5 colleagues have for FDA. We hope these resources will
6 aid the agency's support activities that can facilitate
7 resolution of shortages in the future.
8 As you can see, our proposed solutions are
9 two-fold. One: We recommend FDA reallocate resources
10 within its authority to DFP and other activities to
11 ensure those efforts have sufficient resources to
12 address this important national problem. Two: We
13 recommend that if reallocation of resources within FDA
14 is insufficient that FDA be authorized the appropriate
15 funding to prevent of mitigate drug shortages.
16 Another thing that surfaced through our
17 discussions was the lack of adequate and complete
18 information on the scope and duration of specific drug
19 shortages. That's been a theme I think this morning.
20 The discussions of information flow have
21 focused on two different gaps: First being timely
22 communications from manufacturers to FDA on impending

1 shortages, and the second being timely and accurate
2 information to providers when shortages occur.
3 Though many act on a voluntary basis,
4 currently manufacturers are not required or required in
5 limited capacity to notify FDA about shortages. Public
6 notification of the scope of duration of shortages is
7 often based on voluntary reporting, aggregated report
8 data, and communications with manufacturers. Providers
9 are often the last to know of a shortage and are forced
10 to make complicated decisions on the care of patients
11 with limited or no substantive information.
12 I know that some of my industry colleagues
13 have expressed interest in earlier notification
14 requirements but also recognizes some unintended
15 consequences can result depending on the specific
16 requirements. For example, earlier notification
17 requirements may increase hoarding of drugs, again a
18 theme we've heard this morning. Also, the definition
19 of shortages may need to expand beyond manufacturing
20 issues to also include distribution problems.
21 As a result of our discussions, proposed
22 solutions that rose to the surface include the

1 following. First, require manufacturers to report
2 discontinuations and interruptions six months in
3 advance or upon determining production will not meet
4 average historic demand. Second, establish
5 communications methods to provide accurate and timely
6 information on drug shortages to providers. And third,
7 to establish methods to better predict the seriousness
8 and duration of drug shortages.
9 Now I'd like to turn over the presentation to
10 Julie Reed, who will discuss three additional issues.
11 MS. REED: Thank you, Jason. I'm Julie Reed,
12 the Vice President of Government Affairs for Hospira,
13 and Hospira is pleased to be a member of the Drug
14 Shortage Summit, and we are committed to working toward
15 solutions to resolve and prevent drug shortages.
16 As Jason noted earlier, this is a multi-
17 stakeholder issue with many components and causes; and
18 the solutions for solving drug shortages are a work in
19 progress and very complicated. After Jason and I
20 finished outlining the Summit's recommendations, we'll
21 turn the rest of the afternoon over to the remaining
22 stakeholders to talk about how all of us in this room

1 could continue to work together to solve this crisis.
2 With issue 3, the Summit folks found that
3 there was a lack of contingency plans for critical
4 drugs that are vulnerable to shortages. The proposed
5 solutions were, one, establish criteria for determining
6 whether a drug is vulnerable to shortage and designate
7 such drugs as part of the FDA's approval process.
8 Two: Establish appropriate incentives for
9 manufacturing redundancies or other means of producing
10 emergency supplies for drugs deemed vulnerable to
11 shortages. The pharmaceutical industry should
12 collaborate with the regulatory and legislative
13 entities to identify these incentives. This is a
14 partnership. Thank you.
15 (Laughter)
16 MS. REED: Although this sounds like a simple
17 problem with a simple solution, how could you not have
18 a contingency plan to prevent this problem? As we
19 noted by the number of stakeholders involved in this
20 issue and a heavily regulated industry with multiple
21 stakeholders, a contingency plan become complicated.
22 The good news is that the folks in this room and who

1 have participated in the Summit are committed to
2 solving this problem. I need another partner.
3 (Laughter)
4 MS. REED: With issue number 4, the inability
5 to quickly respond to shortage of controlled
6 substances, this is an example of the complicated
7 regulatory environment drugs are supplied under.
8 Regulations for manufacturing and production quotas for
9 controlled substances may limit the ability of the FDA
10 and manufacturers to address drug shortages in an
11 expedited manner.
12 Section 306 of the Controlled Substances Act
13 requires the Attorney General establish aggregate
14 production quotas for each basic class of controlled
15 substance listed in Schedule II. Quotas are set
16 annually in the fall based on factors such as past
17 sales. While manufacturers can request revised quotas
18 at any time, the process is burdensome and prolong and
19 exasperate a drug shortage. The proposed solution by
20 the group is to require collaboration between the FDA
21 Center for Drug Evaluation and Research Divisions and
22 the Attorney General to establish a process that would

1 expedite the increase in manufacturing production
2 quotas when needed in response to drug shortages of
3 controlled substances.
4 The impact of this solution is a process of
5 rapidly increasing controlled substance quotas to firms
6 that can produce these Schedule drug products and allow
7 manufacturers without shortage problems to ramp up
8 production and help resolve shortages or these drugs.
9 With issue number 5, where there's a
10 disincentive to manufacture older generic injectable,
11 many of the current critical shortages involve older
12 generic injectables, some of them over 75-years old.
13 These were approved before there was an FDA. To get
14 these products in line with the current pathway, the
15 agency is working with manufacturers to submit new drug
16 application or NDAs, which for some manufacturers is a
17 costly disincentive to continue the drug's production.
18 Under the current NDA submission requirements
19 for new drugs, filing and NDA application for approval
20 of an older generic drug can be lengthy and expensive,
21 and the cost of the application may not be offset by
22 the revenues the product may generate. The proposed

1 solution from the group is to leverage current FDA
2 pathways to expedite the approval process medically-
3 necessary, unapproved drugs that are vulnerable to
4 shortages without compromising the quality and the
5 safety of the drugs.
6 The impact of this solution is quicker and
7 less costly approval for these medically-necessary,
8 older drugs, which may incentivize manufacturers to
9 initially reenter, enter, or remain in the market and
10 producing, and keep producing such critical therapies.
11 Jason and I have quickly outlined the good
12 work of the Drug Shortage Summit participant. And as
13 folks can see, solving these shortages is complicated
14 and requires the ongoing good work of all the
15 stakeholders. That is why we are all here today. That
16 is what we're trying to do, and we will continue to
17 work together to solve drug shortages. And for the
18 remainder of today, we'll continue our dialogue about
19 solutions and what all of us can do to stop these drug
20 shortages. Thank you.
21 DR. COX: Thank you. Now I'd like to invite
22 Bona Benjamin to lead us through the next session.

1 MS. BENJAMIN: Thank you, Dr. Cox. I'll
2 introduce myself. My name is Bona Benjamin. I'm the
3 Director of Medication Use Quality Improvement at the
4 American Society of Health-Systems Pharmacists.
5 You might wonder why professional
6 associations have their own panel here today, and the
7 reason is that your professional association acts as
8 your collective voice on important issues. And I can
9 tell you that the associations listed in your agenda
10 under this panel discussion have really proactively
11 acted as your collective voice.
12 During the past year and a half after I
13 because responsible for the ASHP drug shortages Web
14 resource center, the coordination, I have probably
15 talked daily, weekly, monthly with representatives of
16 everyone of these organizations and with the Drug
17 Shortage Program staff at the FDA and with the content
18 supplier of our Web site, the University of Utah, Drug
19 Information System. So it's very heartening whenever a
20 crisis like this occurs, a real national emergency, to
21 see all of the groups coalesce together and reach out
22 and start working on it. And I think that FDA is to be

1 congratulated on holding this Shortage Summit, the
2 shortage meeting, to let everybody talk about the work
3 they're doing.
4 So I believe that I have all my -- these are
5 not all my panel members, but all of them are up here.
6 I think we probably have met the first objective, which
7 is to identify the most serious drug shortages. We've
8 heard a lot from healthcare providers and patients
9 describing the strategies used to support members.
10 Certainly, my panelists can comment on that if they'd
11 like to. What I'd really like to get to is proposing
12 additional regulatory and nonregulatory solutions.
13 So I'm going to walk the questions that were
14 provided for this panel focusing mainly on the last two
15 questions. And if you're on my panel, if you'd just
16 raise your hand to be recognized so that I can
17 recognize and give everybody a chance to talk, we'll
18 move forward that way. And I'm going to be jotting
19 these down and trying to summarize them at the end.
20 The first question I'd like to ask is what
21 drug shortages information do you and your members need
22 to make sure your patients get the care you need? Does

1 anybody feel a need to response in addition to that
2 over what was already mentioned this morning? Yes,
3 Jay. Please state your name and your organization.
4 MR. MIRTALLO: Jay Mirtallo, the American
5 Society for Parenteral and Enteral Nutrition. I'd like
6 to emphasize the main issues for our members and even
7 our nonmembers has been accurately, timely
8 dissemination of information about the shortage. The
9 other thing is the absolute ability -- and we've
10 appreciated the dialogue we've had with the FDA -- of
11 developing two-way dialogue so we can get information
12 to them as quickly as possible to what's coming in from
13 our membership, through our listservs, and through our
14 committees that work on drug shortages.
15 MS. BENJAMIN: Thank you. And other
16 comments? Okay. ASCO.
17 DR. HAGERTY: Thank you, Bona. I think in
18 oncology, as we touched on this morning, that I know
19 for some other specialties advanced notice apparently
20 they don't find that helpful in terms of our ER
21 colleague. But in oncology at least, there are
22 certainly setting where you can try to use alternate

1 regimens or there are other treatments that are
2 available; and if you know that in advance, then you
3 can reserve the critically-needed drugs for the
4 situation where it's needed most.
5 So certainly, advanced notice is something
6 that our members are very interested in.
7 MS. BENJAMIN: Thank you, Karen. Others?
8 If not, I'll move to the next question. In
9 addition to drug shortage information, what other
10 resources would help you and your members manage drug
11 shortages more effectively?
12 Well, I'm the ASHP panelist, so I'm going to
13 recognize myself. For us, I believe that since we do
14 have publicly-posted information on drug shortages the
15 most common things we hear from our members is it's too
16 little too late. And it sometimes hits in the area of
17 accurate information, but sometimes it misses the mark.
18 So just to echo what my colleague from ASCO
19 has said, we need to know how much product is
20 available; and if there isn't any available, when will
21 it become available again because the ability to plan
22 care is key. Most of our pharmacists have been

1 managing shortages for quite a while with physicians
2 and nurses and patients being completely unaware of it.
3 It's just now since they've escalated so quickly in the
4 past year that there has been an increased public
5 awareness.
6 So that's the result of a lot of scrambling
7 behind the scenes to make sure that drugs get where
8 they need to be when they're needed.
9 MS. BENJAMIN: AHA.
10 MS. SCHULMAN: We talked earlier about the
11 need for an advanced warning system so that healthcare
12 facilities and physicians can plan for how they will
13 use the limited supplies of a drug until the shortage
14 can be resolved, but if hospitals or other providers
15 are forced to purchase drugs off contract from
16 secondary distributors -- and I'm not just talking
17 about gray market; I'm talking about legitimate
18 secondary distributors -- what would be extremely
19 helpful is some additional transparency to know where
20 those drugs came from and in whose hand they had been;
21 in other words, drug pedigree information. I think
22 that would be provided prior to purchase so that they

1 know that these are legitimate and safe to use on their
2 patients.
3 In addition though, addressing the gray
4 market issue, I think we need better enforcement of
5 whatever existing state laws there are, and I can't --
6 I don't really know -- I'm sure there are state laws
7 around price gouging, but to the extent that those laws
8 can be enforced and information provided to healthcare
9 providers about how to report instances of prices
10 gouging.
11 MS. BENJAMIN: Thank you, Ros. Mike and then
12 Dr. (inaudible) -- sorry.
13 MR. COHEN: Again with the gray market, I
14 just have to bring something up again. We've called
15 some of these folks, and of course, they all tell us
16 they're not part of the gray market; they're all
17 secondary wholesalers. And maybe that's true. I don't
18 know how to differentiate them is basically what I'm
19 saying. We need a way to do that. Maybe they are in
20 fact -- I know this sounds nabut maybe they are in fact
21 providing a service in that I know they do move drug.
22 Sometimes, we heard earlier today, that there

1 may be regional shortages. Well, one of the things
2 they tell me they do is they find drug in one region of
3 the country and move it to others. They tell us that
4 the price increases are -- they don't have a situation
5 where they can participate in a chargeback mechanism
6 set up by a group purchase organization through
7 contracts for that organization.
8 I don't know whether any of this is true or
9 not, but it does seem like we need somebody to help us
10 and give us some guidance and certainly make sure, as
11 you say, that we have -- or you say Roslyn -- pedigree
12 information for them.
13 I just -- I don't know. It just seems like
14 we are shooting in the dark. We're taking a big risk
15 when we use these organizations. If they're going to
16 be out there, if they're going to be functioning, if
17 they're legal, which they are apparently, we need to do
18 more than what we're doing to help organizations and
19 give them some guidance on which one are good and which
20 ones are not or whatever.
21 DR. BERRY: Yes. I'm Arnold Berry from the
22 American Society of Anesthesiologists, and I'd like to

1 make a different comment on a different area. That is
2 when drugs are in short supply we talked about
3 alternative drugs that could be utilized, and I was a
4 little bit surprised in the FDA's data saying that only
5 4 percent of their shortages were due to a ramp up in
6 use of other alternative when a primary drug was in
7 short supply. Maybe this has affected us more in
8 anesthesiology, but this issue of induction drugs, when
9 propofol was in short supply was terribly important to
10 us because at the same time we has shortages of other
11 induction drugs as well.
12 So one of the things that might be important
13 is to make the manufacturers of some of the alternative
14 drugs aware as early as possible of the possible
15 increased use of those medications that they're
16 producing because they may not see the link to the
17 drugs that was in shortage.
18 MS. BENJAMIN: Other? CHCA.
19 MS. BENJAMIN:
20 MR. van EECKHOUT: I'm John van Eeckhout with
21 Child Health Corporation of America. I think one of
22 the issues that we need to address is much better

1 communication among not only the FDA but I think we
2 need to really talk about much more effective
3 communication processes because there is a lot of
4 erroneous information in the marketplace. Routinely we
5 hear from -- we have a very robust group of pharmacy
6 buyers within Child Health Corporation, and they're
7 constantly communicating, and they will move things
8 around from wholesaler to wholesaler.
9 We also have very poor communications in
10 terms of erroneous things coming out like this drug is
11 on allocation, and then suddenly the sky is falling,
12 and they're running around wanting to capture whatever
13 they can when in fact it's not really an issue.
14 I think the other issue -- back to Mike's
15 point about the gray market -- is we do everything we
16 can to discourage the gray market utilization, and
17 actually Premier Bryant Mangum Group has got a person
18 who actually has looked at -- there's a site on the
19 NABP Web that talks about the authorized wholesalers.
20 And although there are a couple of them on there that
21 are questionable, I think that's a really good
22 reference point for a lot of the buyers to use as a

1 legitimate supplier of drugs.
2 Just communicating those issues I think would
3 be really important and making that really clear to a
4 lot of people. And again, I think that for us a lot of
5 it is a networking issue, but it's worked very well,
6 and we've averted a lot of problems, particularly in
7 the children's hospital area because we've done some
8 things that have facilitated getting drugs at people at
9 the appropriate time.
10 MS. BENJAMIN: Anything else. Oh, Jay. I'm
11 sorry. A.S.P.E.N and then ISMP.
12 MR. MIRTALLO: Jay Mirtallo, A.S.P.E.N.
13 There's two issues related to further ways to help
14 communicated information. Communication is a big issue
15 to us of getting out recommendation to clinicians. And
16 I think it's really important related to parenteral
17 nutrition the education and training of individuals in
18 healthcare societies whether it's a pharmacist,
19 physician, nurse, or dietician is inconsistent at best.
20 And when these shortages occur and they have to modify
21 away from -- go away from their standardized approaches
22 toward what they do, they really have huge questions

1 "And what do we do now?" "What's the alternative? How
2 is it used?"
3 The other issue is because it's a nutrient,
4 as Mike has mentioned, if they don't have a nutrient or
5 would give us an optimal dose, they developed
6 efficiencies. So those have to be monitored.
7 We really are in favor of getting good
8 information out to our members and to AHSP members, but
9 we see a lack of dissemination out to people that don't
10 know some of the time what they don't know about how to
11 deal with a drug shortage related to our areas. We had
12 suggested perhaps we do need to have a nation
13 clearinghouse for some of those guidelines or practice
14 management information as well as the other drug
15 shortage information about why it happened, when it's
16 going to occur, and when it's going to be back on the
17 market.
18 So that's the one comment of perhaps
19 developing a national clearinghouse Web site for all of
20 our guidelines and recommendations for how to deal with
21 that. For smaller organizations, they'll have the
22 resource staff, say, in neonatology or in parenteral

1 and enteral nutrition that can be there to help them
2 through the shortage problem.
3 The second point is this is an unprecedented
4 area for us in that in all other shortages for
5 parenteral nutrition very small, very few
6 manufacturers. There's consolidation in the industry.
7 Vitamins have been the biggest issue for us over the
8 past couple of decades. We've never seen it occur so
9 much so frequently. There's only been one component of
10 parenteral nutrition that has not been affected by the
11 shortage; that's dextrose. All the other 11 or 12
12 different components have been affected at some point
13 in time during the last year. I think only one of
14 which has been resolved.
15 And the unprecedented area is that is has not
16 been resolved. All of our recommendations in the past
17 have been six months, have been a year the issue has
18 been resolved. We see no end in sight.
19 So one of the other points we'd like to
20 address at what point do we get a critical mass where
21 our patients are more prone to electrolytes, vitamin,
22 trace element disorders that we ask to see a

1 facilitated process for us importing drugs from some
2 other safe areas and being able to assure that.
3 MS. BENJAMIN: ASA.
4 MR. COHEN: Yes. At the risk of being a
5 little repetitious, I wanted to bring up what I
6 mentioned this morning regarding the sterile
7 compounding pharmacies and the response that they
8 sometimes make when there is a drug shortage. There
9 are those out there that can respond very quickly, and
10 they'll get drugs out to you in a few weeks as a matter
11 of fact.
12 When manufacturers are not able to supply
13 drugs that we absolutely need, these folks they're out
14 there, and people use them. We just feel that -- they
15 haven't been properly vetted for us. We don't know
16 which ones to use, which ones not to use. We don't
17 know which ones are following regulation, if they even
18 exist in their particular state, which one are
19 manufacturers, which ones are providing sterile
20 injectable pursuant to an individual prescription.
21 It just seem to me if we're going to live
22 with this situation -- and maybe that's what we have to

1 do -- then we need FDA or maybe it's another
2 organization. I'm not sure, but we need somebody to
3 recognize these pharmacies whether it's certification
4 or registration or accreditation or what. We'd like to
5 know which pharmacies are following all the
6 regulations, the requirement -- maybe it's good
7 manufacturing practices is what I should be saying, and
8 we don't have a way of doing that. It's not clear, and
9 it's absolutely needed.
10 MS. BENJAMIN: Other thoughts about what
11 other resources? Ilisa.
12 MS. BERNSTEIN: Hi, Ilisa Bernstein. I'm
13 going to jump in. I know you're looking for
14 suggestions from the panel, but based on what I've
15 heard, with respect to the gray market it sounds like
16 there needs to be some education on what the gray
17 market is because is somebody can't -- if the drug is
18 in shortage and you can't get it anywhere and all of a
19 sudden you have these offers to get it, you got to
20 wonder, and you got to be suspicious about it.
21 And it sounds like there are people that are
22 taking advantage of healthcare professionals and

1 pharmacists who are in desperate situations, and some
2 education may be needed whether from FDA and others in
3 the healthcare professional community. Thanks.
4 MS. BENJAMIN: Anyone else? CHCA.
5 MR. van EECKHOUT: In the regulatory arena,
6 one of the things that we're starting to see amongst
7 the hospitals that CHC represent is beginning of a
8 looming shortage of small doses of narcotics, meaning
9 like 2, 4, 8 mg morphine, 100 m fentanyl. Don't know
10 what's going on, whether manufacturing is moving toward
11 the large products, or what the issue is.
12 But as everybody knows, the DEA has a
13 calendar year approach to the allocations that they put
14 on the manufacturers. So I'm beginning to wonder 4th
15 quarter here is going be a real problem for these types
16 of products. And I hear from all the buyers, "We have
17 a problem. I can't get this. I can't get that." The
18 only thing that's available is the jumbo size of
19 fentanyl, which is a lot of wastage from them.
20 I think that if there is a way we can maybe
21 get the regulatory people to pay more attention to the
22 smallest, most vulnerable patients that we serve,

1 particularly in terms of analgesics I think that would
2 be something that would be worth looking at. I think
3 sometime we just sort of get forgotten because we just
4 assume everything is going well, but in reality, I
5 don't think it's quite that easy.
6 MS. BENJAMIN: Before we move to the next
7 question, I'm going to recognize myself again just to
8 clarify something that was talked about earlier about
9 information about therapeutic alternatives for drugs
10 that are in shortage. This is actually the reason that
11 there are two drugs shortage Web resource centers. FDA
12 monitors medically-necessary drugs. ASHP's site lists
13 all the drugs that are in shortage, which comes from
14 voluntary reports that we receive. And in addition
15 because we are contracted with the drug information
16 service, we also put drug information on that Web site.
17 And Erin Fox and I have talked about a lot of
18 the issues that many of you are talking about here:
19 What are the comparative pharmacotherapeutic things
20 that need to be considered among all the anthracyclines
21 for instance? What are the equally analgesic doses of
22 all the opiates? What are the comparative

1 susceptibilities of the various antibiotics? We really
2 have recognized that practitioners can't run around and
3 do this at the last minute, which is when they hear
4 about the shortage, so we tried to anticipate that by
5 putting the information on our Web site.
6 Okay. I'd like to go to the next question,
7 which is really a two-part question. How does FDA
8 assist your organization with drug shortages? And what
9 recommendations do you have to improve this assistance?
10 And you have FDA's ear now, so I encourage all of you
11 to speak up.
12 (Pause)
13 MS. BENJAMIN: Nobody raises their hand.
14 (Laughter)
15 MS. BENJAMIN: Okay. Well, I'll go first.
16 At ASHP, we work on at least a weekly and sometimes a
17 daily basis with the FDA Drug Shortage Program staff.
18 We are very much aware in our organization of the
19 yeoman's job that this group does trying to manage drug
20 shortages and reduce the impact of these shortages on
21 patient care. The individuals in this program staff
22 are very, very receptive to comments from practitioners

1 or from anybody -- patients, or anybody that calls that
2 has a question about a shortage. We know that they
3 have done some extraordinary things in the background
4 to pull off maintaining a supply at the practitioner
5 level.
6 On our side, what we do for them is report
7 sometimes the disconnect between the manufacturer has
8 gone out and gone back up to full capacity production
9 and the availability of the drug at the point of care,
10 which don't always match up. So our members and the
11 groups that we work with are kind of their eyes on the
12 field, and they're kind of our eyes in the background
13 of the regulatory area.
14 Does anybody else here work directly with FDA
15 and can comment on your relationship? ASA.
16 DR. ARNOLD: I think it's critical to have
17 this relationship with FDA, and ASA likewise has had
18 this very close working relationship with FDA. I want
19 to publicly thank FDA for their work in the spring of
20 2010 with the importation of propoven, that is the
21 European formulation of propofol, which alleviated the
22 shortage that our members had for this drug which has

1 become so important to our practice.
2 So I think this is clearly something that FDA
3 did to benefit anesthesiologists and the patients that
4 we care for.
5 MS. BENJAMIN: Thank you, Dr. Berry. CHCA.
6 MR. van EECKHOUT: Yes. Commenting on
7 working with the FDA. I worked very closely with Val
8 and other people particularly on thiotepa shortage
9 issues and the oncology issues, and I think you've been
10 extraordinarily responsive in dealing with this issue.
11 And I think your collaboration with AHSP and Erin Fox
12 is superb in terms of keeping information out front and
13 keeping people fully aware of the circumstances.
14 I think in some cases people feel that you
15 are kind of like Thor the superhero; you can just throw
16 you hammer and --
17 (Laughter)
18 MR. van EECKHOUT: -- make everybody bow down
19 and do whatever you want them to do. Unfortunately,
20 that's not the case, and I think that's a realization
21 that we've all developed of late. But I think that
22 you've done and incredibly good job in terms of dealing

1 with this issue, and we appreciate all the information.
2 And you know I routinely email you a lot, so I
3 appreciate your correspondence back. Thank you.
4 MS. BENJAMIN: Thanks, John. A.S.P.E.N.
5 MR. MIRTALLO: Jay Mirtallo from A.S.P.E.N.
6 Just one other comment. Again reiterating how much
7 we've appreciated the dialogue we've had over the last
8 couple of years with regards to our situations as well
9 as our follow-up. We do have people in our staff that
10 are monitoring routinely what's going on that the FDA.
11 The only thing that they have come up with as
12 far as suggestion that might help our communications is
13 when there's an update that's posted it's very
14 difficult to discern exactly what that update is. You
15 have to kind of compare it back to your old notes. Is
16 there some way that that can be highlighted what the
17 update is to make it easier for our staff to highlight
18 what those changes are? It would be greatly
19 appreciated.
20 MS. BENJAMIN: An professional associations
21 thaw have an as for the FDA? Dr. Cox, we don't have
22 an open comment period after this. Do you want to open

1 that question up to the audience to give you some more
2 information?
3 DR. COX: I think that's fine.
4 MS. BENJAMIN: Does anybody in the audience
5 want to comment on how you've worked with FDA? And if
6 you have not what you would like to see FDA do in
7 addition -- improve their assistance to you?
8 You must be doing a great job. I don't see
9 anybody getting up. (Laughter) Oh, here we go.
10 Can't hear you Judi.
11 Go to the center, or you can come up here.
12 MS. JACOBI: Judi Jacobi, past president of
13 the Society of Critical Care Medicine. And I think one
14 of the things that potentially is an opportunity for an
15 organization such is our as we work with our members to
16 deal with shortages and use alternatives appropriately
17 and effectively is to recognize that most of what we
18 use in critical care for ongoing supportive patients --
19 and certainly this could be true in adults and is even
20 more true in pediatrics -- is going to be really
21 discussing drugs in a very off-label fashion. So at
22 some point certainly some collaboration with those

1 alternative agents and discussion about how we can more
2 effectively prepare our members to use those
3 alternative agents appropriately since the FDA may have
4 a say or an interest in what we're recommending to our
5 membership.
6 MS. BENJAMIN: Thank you. The center
7 microphone.
8 DR. BANK: Yes. Hi, my name is Ron Bank. I'm
9 an anesthesiologist, Northern Virginia, and I had on
10 question. I apologize. This was addressed earlier,
11 but one thing -- obviously and drug shortage is
12 important to the folks that are affected by it, but as
13 I'm sure my colleges in anesthesia could attest to some
14 drugs there's really no substitute such as
15 succinylcholine, which is a critically important muscle
16 relaxant that we use in anesthesia, and we had a
17 shortage of that a while back. It was very concerning.
18 It's really a very critical drug for patient safety in
19 treating, amongst other things, when the vocal chords
20 spasm and come together and a patient cannot be
21 adequately ventilated.
22 But my question is -- and I appreciate the

1 FDA holding this forum very much -- my question is has
2 there been any thought given to maybe prioritizing what
3 drugs that are under shortage must get attention more
4 rapidly or fast-tracking drugs that the FDA could maybe
5 give more attention to than some other that maybe
6 aren't necessarily as immediately critical as a drugs
7 succinylcholine or other such drugs to some of the
8 chemotherapeutic agents because some these drugs there
9 is no good substitute for, and they're very critical
10 drugs to the lives of our patients? But thanks for the
11 forum. I very much appreciate it.
12 DR. COX: So we do is we're looking at drugs
13 that are in shortage, we look at those that are
14 medically necessary, and we do work to try and resolve
15 shortage issues as quickly as possible whether it be
16 through trying to mitigate the risk from the existing
17 product if there's a deviation where that's appropriate
18 to do so, again, the filter example that I presented
19 earlier; or working with manufacturers to get other
20 lines up and running or alternative supplier, the
21 necessary components in order to be able to get drugs
22 to patients quickly.

1 So we do based on medical necessity, looking
2 at the risks and benefits of the product, the
3 criticality of the need, to try and respond as quickly
4 as we can to restore supply or prevent shortage
5 whenever possible. So there is an awareness of those
6 issues.
7 DR. BANK: Thank you very much. I appreciate
8 it.
9 MS. SMITH: Hi, my name is Linda Smith. I'm
10 an individual pharmacy consultant in the state of
11 Maryland. I'm here representing the Maryland
12 Association of American Society of Consultant
13 Pharmacists, and I just had a question. When you look
14 into the issue of drug shortages, how much of that is
15 being affected by things that are happening around the
16 world and nonavailability of raw materials going into
17 the production process?
18 CAPT JENSEN: This is Val Jensen, Drug
19 Shortage. I'll note that the raw materials --
20 shortages that were related to raw material in 2010
21 actually a small number were related to just solely raw
22 materials issues, so less than 10 percent of shortages

1 were related to that. And we continue to see that this
2 year as well that's it's a fairly small number that are
3 related to just solely raw material issues.
4 But we do have shortages that are finished
5 product shortages that are global shortages, so these
6 are shortages that are occurring in all countries.
7 We're sharing information with other regulatory
8 agencies so that we can share information about those
9 shortages that are occurring, and we're continuing to
10 do that.
11 MS. SMITH: Okay. And I wanted to make one
12 other comment. I've been to an ASCP meeting where a
13 journalist, an investigative journalist, who wrote a
14 book called Dangerous Doses, came and spoke to us. And
15 I found out at that conference that even going through
16 your major wholesalers they maybe buying on the
17 secondary market, and you can't always be assured that
18 even with the primary wholesalers that you're getting
19 what you think you're getting. And I think we really
20 need to be looking at this more closely as a country in
21 terms of what's going on there.
22 DR. COX: Thanks for your comment. We

1 recognize the critical importance of product quality,
2 and you're raising a question about delivery of product
3 and such, so we appreciate your comment. Thank you.
4 MS. BENJAMIN: AHA.
5 MS. SCHULMAN: I was having difficulty trying
6 to answer this question because as we all heard other
7 folks around the table have said FDA has done
8 everything humanly possible, especially the Drug
9 Shortage Program, with the limited staff and the
10 resources that are available to address drug shortages.
11 They've done a terrific job.
12 So the only thing I can think of actually is
13 to reiterate what's already been said around the need
14 for the department at the higher level or FDA at the
15 higher level to continue to allocate additional
16 resources toward this issue of drug shortages through
17 allocating resources, additional staff to the Drug
18 Shortage Program as well as perhaps to also establish a
19 mechanism for more formal communication between the
20 Drug Shortage Program and other parts of FDA that
21 obviously also plan, just like the Office of Generic
22 Drugs and the compliance folks.

1 So maybe a more formal office, a stronger
2 message at the highest levels at FDA that these sorts
3 of issues are a national crisis and that they need to
4 take priority to get the right drugs to the patients at
5 the right time.
6 DR. BERNSTEIN: Could I just comment on that?
7 Just going back to what Ed showed in your slide.
8 There's tremendous communication across FDA
9 particularly within CDER with Drug Shortage Program,
10 Compliance, Office of Generic Drugs, Office of New Drug
11 Quality, Assessment, all over, and the Office of
12 Regulatory Affairs in the field.
13 So if there is a shortage, we put the
14 resources that are needed in order to figure out what
15 has to be done. A lot of what they do is really
16 coordinating and helping and reaching out a lot to your
17 organizations, but I can tell there are a lot of other
18 resources that the agency puts toward helping alleviate
19 and mitigate and prevent shortages.
20 MR. SCHMUFF: Yes. If I could just add --
21 this is Norman Schmuff from ONDQA. The interaction
22 with ONDQA, Office of Generic Drugs, and the Office of

1 Compliance is essentially a daily interaction, and
2 there is a coordinator in Office of Generic Drugs, and
3 that would be Harvey, and the Office of New Drug
4 Quality Assessment, me; and there is an entire staff in
5 the Office of Compliance that deals with drug shortage
6 issues.
7 So I think we have it covered I think
8 reasonably well, and I think it is no exaggeration to
9 say that the interaction is daily with those groups.
10 CAPT GREENBERG: I do have interactions with
11 Val and Compliance, and it's a daily thing, and it's a
12 daily thing with Erin and her group and ASHP. We do
13 talk every day probably more than once or twice a day,
14 but there's a good communication among us. I may not
15 reach out to a lot of the associations, but I do have a
16 lot of contacts in the industry to investigate these
17 issues.
18 MS. BENJAMIN: Bona Benjamin from ASHP. I
19 have a question. So it sounds like communication
20 within the agency those channels have been established.
21 Is there communication among the different agencies at
22 the higher Federal level? Because we've heard other

1 regulatory groups mentioned.
2 DR. BERNSTEIN: This is Ilisa Bernstein. So
3 when Dr. Kweder was here earlier, she mentioned that at
4 the Department of Health and Human Services at that
5 level there is a group coordinating, looking across HHS
6 trying to address this and looking at solutions as
7 well, not only just what HHS can do but what others can
8 do as well.
9 And just to add on top of what you were
10 saying is so that we're working together. We actually
11 have formalized SOPs. This is all a really good,
12 strong network of communicating among the agencies.
13 MS. BENJAMIN: And would you say that is part
14 of the reason that you're able to get advanced
15 notification from the field in time to avert drug
16 shortages?
17 DR. BERNSTEIN: I'm not really clear what
18 your question is. Are you saying that from the field
19 finding out about? Because there's a difference
20 between advanced notification that I'll let Val and the
21 other is Drug Shortages in terms of knowing when a
22 company will be disrupting production or discontinuing

1 production at the earliest point is extremely helpful
2 and important. Where that information comes in, to get
3 that information to the agency, and then letting the
4 Drug Shortage Program kind of work with that and work
5 with the rest of us is important.
6 I think what you were saying is in the field
7 in terms of -- you mean just anybody out there?
8 MS. BENJAMIN: For instance, if any
9 enforcement action is being contemplated that might
10 cause a drug shortage.
11 DR. BERNSTEIN: When there's a problem with a
12 product -- so there's metal shavings or glass or
13 something in an injectable, or we'll get a report to
14 the agency somehow, either manufacturer or pharmacist
15 or healthcare professionals will give us a report. We
16 will then follow up on that problem. That may then
17 result in an inspection at the facility where the
18 product is made. Then depending on a whole bunch of
19 series of events, if there is a product that's
20 medically necessary that manufactured at that facility,
21 we will work very closely with that company in order to
22 figure out how they can fix the problem while they're

1 continuing to manufacture a quality product so that
2 that medically-necessary product can continue.
3 It's just a lot of -- every case is
4 different. It's all case by case, but the communication
5 between FDA and the firm whether it be their product
6 quality folks or the folks that are dealing with
7 production and making sure that it continues. That's
8 all extremely important, and I guess we're going to
9 talk about that at a later panel, so...
10 MS. BENJAMIN: Yes. I think maybe the
11 industry panel. I'm going to go to the last question
12 for the healthcare professional group panel. What
13 actions does your organization recommend for other
14 stakeholders such as industry, distributors, group
15 purchasing organizations, other Government agencies to
16 help prevent or reduce drug shortages?
17 Anybody got any ideas for any of our other
18 stakeholders? FDA is not the only one in the mix.
19 CHCA.
20 MR. van EECKHOUT: John van Eeckhout again.
21 I think that one of the issues that we're all
22 struggling with is, is the pharmaceutical/industrial

1 complex in the United States so old and so decrepit
2 that we're having -- is one of the cause of the
3 problem? And are we facing the potential of a
4 globalization process whereby everything is going to
5 move to the Pacific Rim, where obviously the API is
6 now, etcetera?
7 If that's the case, then the whole milieu for
8 the FDA is considerable different than it is now in
9 terms of getting over there and inspecting things. But
10 I guess my concern is I'm not necessarily sure that's
11 the best thing to happen for us.
12 On the other side of the coin, is there a
13 possibility that through legislation or some other
14 process with state and local people we can have an
15 incentivized reinvigoration of the pharmaceutical
16 industry in the United States similar to what happened
17 in Puerto Rico not too long ago, like when I got out of
18 pharmacy school, which is a long time ago?
19 I think that there was an incredible amount
20 of activity in Puerto Rico. A lot of companies moved
21 down there and are still there. And I think that we
22 really need to take a close look at whether we're going

1 to lose this business and this industrial complex or
2 whether we're going to keep it.
3 It's an interesting op-ed a couple days ago
4 by Thomas Friedman saying -- the essential headline was
5 we can have a decade a pain or a century of depression
6 if we don't fix what's going on in this country. I
7 think that applies here also.
8 MS. BENJAMIN: AHA.
9 MS. SCHULMAN: In thinking about what other
10 Government agencies can do, I know we've talked a
11 little bit about payers. A couple of ideas with regard
12 to the Centers for Medicare and Medicaid Services. They
13 probably ought to be working closely with the FDA to
14 ensure that their coverage policies with regard to --
15 Medicare coverage policies can be rapidly changed to
16 permit the coverage and reimbursement of therapeutic
17 alternatives in the event that there is a drug
18 shortage. So we don't see instances in which providers
19 have moved to second or third tier drugs and only to
20 find that the payers say that they're not covered for
21 those indications.
22 Secondly, CMS could -- CMS has a lot of

1 discretionary authority around policies that can
2 temporarily increase reimbursement rates for drugs or
3 for other services. And so one thing that CMS -- we
4 may want to encourage them to do is think about what
5 the options there are in terms of providing for
6 temporary policies to raise reimbursement rates for
7 drugs that are in shortage in order to account for not
8 only the increased prices that providers are paying for
9 these drugs as a result of the shortage but also the
10 other additional cost around it that we've talked about
11 today, cost for managing the shortages in term of times
12 and resources and sourcing additional sources of drugs.
13 MS. BENJAMIN: ASCO.
14 DR. HAGERTY: Thanks, Bona. I'm Karen
15 Hagerty, ASCO. I think from the conversation this
16 morning that it hasn't escaped -- a lot of people's
17 noticed that many of these drugs that are in shortage
18 are the much cheaper sterile generic injectable drugs,
19 and of course, that's part of the reasons that oncology
20 is being hit so hard. And one of the things that we
21 talked about -- I think many of us in the room here
22 testified last week before the committee, and of the

1 things that we talked about was looking at incentives
2 to make these drugs more attractive for manufacturers
3 to make if indeed that is the problem. And I think it
4 would be -- as we said at the time, we don't really
5 think that we're the entity to be suggesting
6 specifically what these incentives are. As we are not
7 in the business of manufacturing drugs, we don't know
8 what would be the most appealing. But we would very
9 much like to hear from those in the industry if that is
10 in fact the case what would incentivize you to get in,
11 stay in, and remain in the business of making these
12 drugs.
13 MS. BENJAMIN: Anyone else? AHA.
14 MS. SCHULMAN: I had one more. We talked
15 about the gray market earlier and a lot of the
16 confusion around what's gray market, what does it
17 really mean, what's legal practices, what are illegal
18 practices. I think there is a real need -- I think all
19 of this calls for some sort of an investigation. I
20 don't know, Department of Justice or Inspector General
21 level kind of investigation of gray market practices
22 including issues like how do they predict the shortages

1 before anyone else knows there's a drug in shortage?
2 Where do they obtain the drugs? And what steps need to
3 be taken to strengthen Federal or state law to prevent
4 unscrupulous secondary distributors from taking
5 advantage of drug shortages through hoarding and price
6 gouging practices.
7 MS. BENJAMIN: A.S.P.E.N.
8 MR. MIRTALLO: Jay Mirtallo from A.S.P.E.N.
9 One of the things we've added to our additional things
10 that we'd like to get support for is realizing that
11 with the shortages we're dealing with suboptimal doses
12 of a lot of nutrients as well as a huge change in some
13 of our systems that have been standardized for dozens
14 of years of any types of errors or adverse events that
15 have occurred as a result of that that we get reported
16 to organizations like ISMP so that we can look at those
17 on an individual basis from a seminal event standpoint,
18 but also we can aggregate the data to take a look at
19 our systems, which I think would be particularly
20 important in oncology areas as well as in our areas of
21 parenteral and enteral nutrition; especially when we
22 deal with interdisciplinary care where a great deal of

1 people are dealing with patient care like we heard
2 Davria Cohen mention her dietician that takes care of
3 her.
4 Well, dieticians aren't familiar with the
5 pharmaceutical supply chain. They're not familiar with
6 a drug error or a medication errors. They look for
7 pharmacists to do that, but they are actually on the
8 frontline of thing on quite a few occasions.
9 So that's one of the things we're suggesting
10 we get the information out to groups that have -- that
11 touch the patient, that can get that information into
12 an area of experts that can deal with it to make
13 better, safer recommendations for therapy even during
14 times of a drug shortage.
15 MS. BENJAMIN: Yes, ASA.
16 DR. BERRY: One of the themes today has been
17 timely communications both with FDA regarding the
18 possibility of production problems and also
19 communication with the practitioners. ASA supports the
20 Drug Shortage Summit work group and their
21 recommendations to broaden the reporting requirements
22 to the FDA beyond those drugs that are classified as

1 medically necessary when the manufacturer knows of a
2 production problem or is anticipating discontinuance of
3 a drug. So I think that recommendation becomes very
4 important in beginning the communications both with FDA
5 and with the provider.
6 MS. BENJAMIN: Anything else? I'm going to
7 go last, so speak now or forever hold you peace. So
8 speaking on behalf of ASHP and having the relationship
9 with the FDA Drug Shortages Program staff that I have
10 plus all of my colleagues inter-professional as well as
11 all my stakeholder colleagues, what we have seen from
12 our position of trying to monitor this on the national
13 basis, there are four things I think that are really
14 important. One is the pharmacists and patients and
15 physicians, everybody needs to be assured of the
16 integrity of a drug product, so we support FDA's strict
17 regulations and their oversight of the safety and
18 quality of the drug supply.
19 We would also like to be able to ensure the
20 integrity of the supply chain. We would like to know
21 where a drug came from, where it's been before it gets
22 into our hands as the end user. We have tried to sort

1 of sketch out the processes and all the moving parts
2 that have to do with drug shortages, and it's very
3 hard. We would like to see someone do a pretty deep
4 dive on this subject, someone with expertise in a lot
5 of fields, in globalization of business and finance and
6 economics, and pharmaceutical manufacturing, and in the
7 use of medications worldwide.
8 We also agree with the rest of the panelist
9 and many of you in the audience that better
10 communications are needed. We know because of our
11 interaction with Val and her staff that a lot of what
12 they know they cannot tell us because it's proprietary
13 information. But we also know that when we go to talk
14 to our patients or to our physicians or to our hospital
15 medical staff and corporate leadership that the answer
16 to the question why are we having as shortage, we don't
17 know, is just not acceptable.
18 So we would like to work with FDA and others
19 to find a level of communication that gives enough of
20 an answer so people understand that this is just not
21 some big, black box that nobody knows what's going on
22 inside of.

1 We would also like to secure those
2 communications between the FDA and our group and the
3 healthcare providers themselves. We are aware that
4 this information is often obtained by other whose
5 motive is not to improve the care of patients.
6 And we urge everybody to support the two
7 bills that are in the legislature right now. We have
8 only one change, which was we would change them to say
9 that they should cover all drugs regulated by the FDA
10 not just approved drugs. But we really believe and we
11 think it's been proven by FDA's own statistics that
12 while this is not the solution it is one solution, and
13 I think everybody here in this room who has dealt with
14 drug shortages knows that we need all the help we can
15 get right now.
16 So with that, I'm going to end my part of
17 this program and turn it over to the next panel.
18 DR. COX: Thanks, Bona. Now we'll go to
19 Susan Winckler from the FDA Law Institute who will
20 carry us through the next few sessions. Susan.
21 MS. WINCKLER: Great. We've reached the
22 point in the afternoon where we have two speakers, four

1 panelist, four questions to answer, and 15 minutes. So
2 I am going to save time by staying right here, and
3 Michael, if you go to the podium, I'll briefly
4 introduce this panel.
5 We've been working backwards through the
6 supply chain from this morning hearing from the
7 patients who are directly affected to then the point of
8 care providers and the healthcare professional
9 associations. We're now at the panel to talk with and
10 to hear from and discuss with the folks who operate the
11 supply chain and get this product from one place to
12 another and other show play in this space as well in
13 the group purchasing.
14 So we will hear presentations from Michael
15 Mone with CardinalHealth, then from Bryant Mangum with
16 Premier, and then we will address some questions. So,
17 Michael.
18 MR. MONE: Thank you, Susan. Good afternoon.
19 I'd like to start out with my disclosure as obviously I
20 work for CardinalHealth, and I have a very small
21 holdings in both Pfizer and Monsanto.
22 This is an interesting opportunity to spend

1 five minutes to give you the perspective of the man in
2 the middle. Though I am providing that particular
3 perspective of the man in the middle in this process,
4 it is with an appreciation and a concern for the
5 patients.
6 And the reason that we selected this slide --
7 and it's really a very important slide that we selected
8 -- was that's a patient there, and the entire focus is
9 because at the end of the supply chain is a patient,
10 and the patient is why we do what we do.
11 It's interesting when I listened to the
12 comments this morning about pharmacy and the duration
13 of drug shortages, and I noticed the statistics went
14 back 10 years probably because the speaker earlier, Dr.
15 Fox, is so much younger than I am. But I can tell you
16 that in 1981 when I started the practice of pharmacy,
17 we had drug shortages back then as well. They were not
18 nearly as severe. They were not nearly as
19 demonstrative in quantity, and quite frankly, based
20 upon my perspective, although it is recollection, so it
21 could be subject to debate, I don't think it lasted
22 nearly as long.

1 So what we know today is that we really have
2 an urgent situation. The frequency and the duration of
3 drug shortages are at record levels. We saw the
4 statistics there. We see patient care and patient
5 safety being negatively affected. We heard this
6 morning that those are real cases.
7 So let me submit to you that the data also
8 that we saw -- and I have it in a slightly different
9 framework -- is that the shortages are caused by
10 manufacturing issues. In the data that we saw roughly
11 this morning in kind of a different graph here is that
12 we're really talking about product quality issues,
13 production capacity, product discontinuation,
14 unavailability of raw materials. We heard the
15 comments. We heard the comments about the
16 internationalization of the pharmaceutical API in the
17 industry.
18 I note that when we look at this that we end
19 up coming back to the key thing that we heard all day
20 today, which was communication and coordination.
21 Here is the part where I really got kind of
22 upset at my folks, and I suspect as a pharmacist I get

1 to talk about my folks as pharmacist. When Dr. Blum
2 made the statement -- and he gave an eloquent
3 description of what he faced -- what really frustrated
4 me was the fact that the found out that there was a
5 shortage when he was trying to administer the drug. And
6 then he found out again that that drug was not there.
7 That I think is a failure on my part in communication.
8 This is a systemic situation. It can't be just single
9 elements of the communication process. It has to go all
10 the way through the entire process to where the
11 practitioner knows before he or she is going to try to
12 administer that drug in an emergency, critical
13 situation that in fact that drug is not available.
14 When we look at communications, the other
15 piece that I think is critical is we need some standard
16 definitions. What does drug shortage means? What does
17 the duration means? What is frequency? When do we
18 decide that we have and we're talking the same language
19 about drug shortages? And clearly, it has to be early
20 as possible within the constraints that public
21 information is available, but it's got to be early.
22 It's got to be consistent, and it's got to be accurate.

1 That's the only way that anybody can actually action
2 off of information.
3 Now let's talk about some of the things that
4 CardinalHealth does in their role. When we talk about
5 drug shortages, what I must dispel is that it's not
6 about buying power as who gets what drug. It's about
7 dynamic allocation. It's about allocating available
8 product. And what you do in that distribution process
9 is you dynamically allocate available product. And
10 it's about what the historical purchases have been in
11 the past. It is the fairest way to make a limited
12 resource go as far as reasonable can be used in the
13 supply chain.
14 We communicate what available information we
15 have to our customers as early as we can. In many
16 instances, it's on a daily basis that we will
17 communicate that information. But again, it goes back
18 to the stage that as soon as we get early information
19 it is accurate and it is consistent we can begin the
20 dynamic allocation process earlier in the process and
21 thereby allowing more people to have access to the
22 limited available product when a shortage occurs. And

1 of course, what we're doing is we're dealing with
2 protecting the supply chain in its entirety.
3 I'm going to go to the last slide -- you're
4 all get this -- because here is what I think is the key
5 to mitigate the impact: Manufacturers and FDA provide
6 faster, more accurate, consistent information. I
7 believe that the FDA, AHRQ, ASHP, and other appropriate
8 clinical organizations could identify appropriate
9 clinical alternatives to product in short supply and do
10 that earlier in the process. We're able to be able to
11 allow the individuals that are practicing to make
12 appropriate clinical judgments if they have that
13 information earlier.
14 Providers should continue to buy direct from
15 wholesalers that buy direct wherever possible because
16 what -- Dr. Leigh Briscoe-Dwyer was on CBS, and she
17 talked about not buying from the secondary market, and
18 it was really important because it was important about
19 patient safety. But it's also important because you
20 don't want to encourage the same activity, which is the
21 hoarding of that product and allowing people to disrupt
22 the supply chain.

1 And finally, distributors should allocate
2 product in the fairest manner, and that's based upon
3 past buying practices.
4 So when we encourage dialogue and
5 coordination all the way through the system, between
6 FDA and manufacturers, and pharmaceutical wholesalers,
7 and our customers, and the doctors and the pharmacy
8 staff, we have a better process.
9 The final slide ends with the same slide I
10 started with because at the end of the day it's all
11 about the patient. It was about the patient when I was
12 a pharmacist. It was about a patient when I was in the
13 hospital, and it's still about the patient. Thank you.
14 MS. WINCKLER: Thank you. Well, now hear
15 from Bryant Mangum with Premier.
16 MR. MANGUM: Susan has a quick five minutes,
17 s I'm going to have to speed up.
18 I'm Bryant Mangum, Vice President of the
19 Pharmacy Services at the Premier Healthcare Alliance.
20 Premier is owned by not-for-profit hospitals,
21 healthcare systems, and other providers. Together with
22 our members, Premier aggregates the buying power of

1 hospitals to provide the economies of scale necessary
2 to get the most effective medical supplies and drugs at
3 the best price. Premier represents over 2,500
4 hospitals and 70,000 alternative sites.
5 Shortages are having an adverse effect on
6 patient safety and driving up healthcare cost. Today,
7 I will discuss two analyses that show the scope of the
8 problems and the financial and human toll. I will also
9 offer thoughts on what can be done to address the
10 important issues.
11 In March of 2011, Premier set out to better
12 understand the extent of the problem and the effect on
13 patient care. Through a survey of 311 pharmacists, we
14 found that between July and December of 2010 more than
15 245 drugs were either in short supply or completely
16 unavailable in 2010. Over 400 generic equivalents were
17 backed ordered for more than five days, and many of the
18 drugs noted as back orders in 2010 have remained
19 unavailable and in short supply in 2011.
20 In evaluating the threat of drug shortages to
21 patient safety, 89 percent experienced shortages that
22 had the potential to cause a medication safety issue or

1 error in patient care; 80 percent experienced shortages
2 that resulted in a delay or cancellation of treatment.
3 Drug shortages are also costly.
4 Combined with the results of other analyses,
5 we estimated shortages could cost hospitals $415
6 million annually through the purchase of more expensive
7 substitutes and additional labor cost. So what is
8 Premier doing to help to diminish these costs?
9 Determining manufacturing capabilities during
10 the contracting process to access whether a particular
11 manufacturer can supply the market, Premier looks for
12 alternatives if capabilities don't meet demand.
13 Instituting and early warning system for hospitals to
14 notify Premier of shortages even before they are posted
15 on the FDA Web site. Once notified, we do work with
16 the FDA to provide that information.
17 We're also exploring longer term contracts
18 for manufacturers to create more predictable volumes
19 and stability in the market. We hope in this crisis
20 people will do everything they could to help patients
21 get the drugs they need. Rather, we have seen numerous
22 gray market vendors take advantage of the problem,

1 offering to sell shortage product at exorbitant prices.
2 Over a 2-month period, Premier analyzed 636
3 unsolicited sales offers from the gray market vendors
4 offering to sell shortage drugs. We compared the list
5 price to Premier's standard contract price. The
6 results were appalling. The average markup being
7 offered was 650 percent, and many others were higher.
8 In fact the highest markup was 4,500 percent.
9 In this case, a drug used to treat high blood pressure
10 that normally sells for $25.90 was offered for $1,200.
11 Markups were as high as 4,000 percent for oncology
12 medications; 45 percent of the offers were marked up at
13 least 1,000 percent above normal price; and a quarter
14 was marked up at least 2,000 percent. Highest markups
15 were seen with the chemotherapy agents, infectious
16 disease agents, and sedation and surgery meds.
17 These markups are troubling, but they also
18 raise safety concerns. When price gougers are
19 (inaudible) with products, it begs several questions.
20 Where and how are they getting the medicines that no
21 one else can get? And how can the integrity of these
22 drugs be ascertained?

1 Premier has taken the position that
2 pharmacies should avoid these vendors and stick to
3 purchasing from known primary distributors, but in time
4 of shortages, pharmacy may need to look elsewhere. In
5 these cases, Premier developed best practices to follow
6 whenever purchases are made outside the primary
7 distribution channel. These include asking for and
8 verifying product chain of custody or pedigree,
9 confirming the seller is licensed and not subject to
10 any investigations. But in our view, the best way to
11 stop price gouging is to fix the drug shortage crisis.
12 Private sector initiatives such as those
13 implemented by Premier can only go so far. We ask the
14 FDA to consider shortening the approval process from
15 medically-necessary generic drugs that appear in
16 shortage; encouraging FDA to engage stakeholders in
17 discussion determining whether a drug is medically
18 necessary. The objective here is to prioritize drugs
19 that are necessary for treatment and also may be at
20 risk for shortages.
21 Granting the Drug Enforcement Administration
22 flexibility to adjust quotas that limit the amount of

1 active ingredient manufacturers may purchase for
2 controlled substances, thus limiting their ability to
3 ramp up production when a supplier exist to market.
4 Creating a fast-track approval of new active
5 pharmaceutical ingredient suppliers for medically-
6 necessary drugs in shortage.
7 Working with manufacturers in slowing the
8 trend of requiring raw material outside the U.S.
9 Requiring manufacturers to provide the FDA
10 notification of planned discontinuations or
11 interruption of the manufacture of drugs. This will
12 allow the FDA to time the work with the remaining
13 manufacturers to increase production.
14 And finally, creating a stakeholders
15 committee to advise FDA on market conditions.
16 In closing, I thank the FDA for the
17 opportunity to share what we've learned about drug
18 shortages at Premier.
19 MS. WINCKLER: Very helpful. Thank you. I'm
20 now going to open it up to Ron Hartman with MedAssets
21 for the Health Industry Group Purchasing Association
22 and Anita Ducca, Vice President with the Healthcare

1 Distribution Management Association.
2 I heard recommendations from Bryant and
3 Michael in two categories: The first
4 category being preventing shortages, and then what can
5 we better do to mitigate shortages. What I heard in
6 the preventing shortages had to be with buying direct,
7 and that's just speaking to some of the changes in the
8 supply system, longer term contracts, and planning for
9 discontinuation and better communications.
10 In the mitigating shortages, the idea of
11 standard definition; improved communications, which I
12 think we've heard all day long; fair allocation within
13 the supply system; and then most recently the
14 stakeholder council as well as other things about DEA
15 and some other pieces, but those are just high level.
16 Ron and Anita, as you think about those what
17 might you add to this question of solutions?
18 MR. HARTMANN: Ron Hartmann with MedAssets
19 representing the Health Industry Group Purchasing
20 Association. We certainly support all of those
21 recommendations. I think the thing that we ultimately
22 need to see and want to have is a stable supply chain.

1 We need to have an adequate number of manufacturers of
2 these products to support the demand in the
3 marketplace. There needs to be sufficient competition,
4 and I think to Brian's point and Mike's point really is
5 at the core of solving this problem.
6 There is obviously a lot of factors and a lot
7 of contributing factors that led us to the current
8 situation, but ultimately we need to have a stable
9 market. The healthcare group purchasing industry
10 foster competition among the manufacturers. We create
11 an environment to let that competition play out. We
12 certainly have a need and an expectation on the part of
13 our respective members to bring them competitive
14 pricing, but we also need to support a stable
15 marketplace. And I think all of our agreements support
16 provisions for accommodating shortages and API material
17 or other events that may had been unanticipated or
18 unplanned at the time contracts were put into place,
19 but ultimately, we need to have a stable supply market.
20 MS. DUCCA: First, I want to qualify one
21 thing. The Healthcare Distribution Management
22 Association has as part of its membership criteria that

1 the wholesale distributor that is a member must be
2 buying direct from the manufacturer and selling direct
3 to licensed entities, and most of those, the vast
4 majority, are indeed healthcare providers. So I just
5 want to qualify that before I give you that and my
6 answer.
7 We certainly support many of the things that
8 you are talking about. On some of them, we have due to
9 anti-trust consideration we have limited ability to
10 comment on. But I will comment on the improved
11 communication point that has been raised. We would
12 certainly agree with that.
13 Our members are in constant communication
14 with their suppliers and with their customers on a
15 routine basis. Our wholesale distributors are talking
16 to and sharing information with manufacturer to help
17 with their demand forecasting, so that's a given any
18 way. But what happens in a shortage situation is that
19 they will increase and enhance that communication both
20 with their suppliers and with their customers.
21 So if there's one thing that I would
22 recommend is to keep that line of communication open

1 with your distributors and help them, for example,
2 identify what the alternatives are because they are a
3 step removed from the patient care, and therefore they
4 need your guidance on what alternatives you think for
5 your patients are going to be needed.
6 I'll also just mention to that end that HDMA
7 is putting together some voluntary guidelines for its
8 membership that would help to -- we think will help
9 identify how best to conduct those communications.
10 MS. WINCKLER: Yes, Dr. Bernstein.
11 DR. BERNSTEIN: Thank you. Just to follow up
12 on that. One of the things that we heard several times
13 this morning is the need for fair and equitable
14 distribution in the time of a shortage, and Michael
15 mentioned that you have some sort of dynamic allocation
16 process. I'm just wondering in those guidelines that
17 you're preparing or if you're aware of any best
18 practices for distribution in the event of an actual
19 shortage?
20 MS. DUCCA: Lisa, an excellent question, but
21 that's one of the areas that I have limited ability to
22 comment on under our anti-trust policy because

1 allocation means who you sell to and when and that kind
2 of thing, so I can't really comment on that to any
3 great extent.
4 I can say, however, that most of our members
5 do have systems and programs where they determine in a
6 shortages situation how and when to distribute the
7 product, and it's usually based on historical
8 purchasing practices.
9 MS. WINCKLER: Michael, would you weigh in?
10 That's one of the slides I had you skip over.
11 MR. MONE: Yes, I know. Okay. Dr.
12 Bernstein, what CardinalHealth does is it takes the
13 available supply that it receives, and it distributes
14 that available supply, and the manner by which we do
15 that is a -- for lack of a better term -- a statistical
16 model that takes historical purchasing pattern and
17 mirrors them up and takes the available supply on a go-
18 forward basis so that it is, if you will, a fairer
19 distribution process.
20 In doing so, everyone gets some and nobody
21 gets none, but nobody get everything that they want
22 because we don't have everything that the supply chain

1 would otherwise be able to push to the customers that
2 we have a the time because the manufacturer did not
3 provide us enough to be able to distribute. And so,
4 it's a statistical model that allows us to be fair
5 about the distribution.
6 DR. BERNSTEIN: And just following up on
7 that. In terms of the practice of others, are you
8 familiar -- is that how other companies do it or?
9 MR. MONE: I can't answer that, Dr.
10 Bernstein.
11 MS. WINCKLER: We have one minute, so I'll
12 ask Michael, Bryant, Ron, Anita, what would you call
13 out as the one most important recommendation that's
14 essential from the participants in the supply chain,
15 whether it's the distributors and the wholesalers, the
16 purchasers? What would you recommend?
17 MS. DUCCA: Just make the product.
18 (Laughter)
19 MS. DUCCA: I'll repeat what's said this
20 morning. I think that once you fix that, once you have
21 enough product a lot of the other issues that we've
22 heard about, the gray market, and gouging and so forth,

1 I think those will go away once we have enough of the
2 product.
3 MR. HARTMANN: I would concur. And certainly
4 the communication pieces that we've talked about and
5 hear about as well are critically important.
6 MR. MANGUM: I think one of the key issues is
7 timely information. As a GPO, one of the areas we
8 struggle with when we hear about a potential shortage
9 is the length of time that shortage will occur. Will
10 it be two weeks? six months? a year? Or will that
11 product even come back on the market. And that really
12 doesn't give us enough flexibility to look for
13 alternative suppliers.
14 So timely information from the manufacturers
15 and really the true nature of the issue. If it's a
16 quality issue, how do we work with the manufacturers to
17 truly understand the issues and the problems so we can
18 seek alternative medications for our members.
19 MR. MONE: Susan, I think if you take the
20 first slide that talks about early as possible,
21 consistent, accurate information with a clear set of
22 definitions so that everyone's working off the same

1 definitions of what those words mean you end up with
2 going to the last slide that I had, the four
3 recommendations there, all working together to resolve
4 a problem that is fundamentally a manufacturing problem
5 after the fact.
6 If you solve the problem, as said earlier,
7 with the manufacturing, you solve the problem. But if
8 you can't, I think the last slide with the pieces in
9 their addresses really what you're looking for.
10 MS. WINCKLER: Very helpful. Thank you very
11 much.
12 DR. COX: Thank you. So at this point let's
13 take a 15-minute break. So that gets us back, if my
14 math is correct, what, about 2:52?
15 (Off the record)
16 (On the record)
17 DR. COX: We're ready to start again. So if
18 folks could get in their seats, and if we could have
19 our panelists back.
20 Great. Thank you all. I'm going to turn the
21 microphone back to Susan Winckler, who will lead us
22 through our next session on recommendations for

1 solutions from the pharmaceutical industry and another
2 panel discussion. Susan.
3 MS. WINCKLER: For the next hour, we will be
4 hearing from folks in the industry who are actually
5 producing the materials as well as from their
6 associations. We have two presentations and then a
7 panel discussion similar to what we did in the last
8 session.
9 To kick off our presentations, we have a
10 longer one from the Generic Pharmaceutical Association.
11 Obviously, the issues have been raised and teed up
12 quite well with all of the prior discussions. So with
13 that, I will introduce Ralph Neas, who's president and
14 CEO of the Generic Pharmaceutical Association. Ralph,
15 your presentation.
16 MR. NEAS: Thank you, Susan. Good afternoon
17 to everyone. My name is Ralph J. Neas. I'm the brand
18 new president and CEO of the Generic Pharmaceutical
19 Association, and I have no conflicts.
20 We thank the U.S. Food and Drug
21 Administration for organizing this timely and crucial
22 meeting, and we greatly appreciate the time and

1 commitment of all the stakeholders here today. We are
2 also grateful for the good work of the American Society
3 of Health-Systems Pharmacists and the other
4 organizations present in advancing efforts to solve the
5 drug shortage crisis.
6 We at GPhA are acutely aware of the
7 distressed caused to patients, families, and clinicians
8 by the shortage of medically-necessary drugs. And on
9 behalf of our manufacturers and associate members, I
10 can state without reservation that the generic industry
11 is devoted to working with every stakeholder to
12 minimize current shortages and mitigate factors that
13 could contribute to future shortages.
14 Before I begin the formal part of the GPhA
15 presentation, I'd like to share with you a few personal
16 remarks. First, this is the 11th day on the job for
17 me.
18 (Laughter)
19 MR. NEAS: And I'm delighted that this
20 workshop is the venue for my first public presentation.
21 I cannot think of a more important public health issue.
22 Second, as some of you may know, GPhA is the third

1 major coalition that I have had the privilege of
2 leading. For 15 years, I served as the executive
3 director of the Leadership Conference on Civil Rights,
4 a 60-years-old coalition of nearly 200 organizations
5 that is the legislative arm of the Civil Rights
6 Movement. For the past several years, I was the
7 president and CEO of the National Coalition on
8 Healthcare, the nation's oldest and most diverse
9 healthcare reform coalition. The 80 organizations
10 represent consumers, providers, businesses, unions,
11 medical societies, minorities, religious denominations,
12 people with disabilities, and many others. And very
13 importantly, I am personally committed to the
14 perspective of patients.
15 Thirty-two years ago, I contracted Guillain-
16 Barrsyndrome, a serious neurological disorder usually
17 reversible, that kept me in the hospital for 155 days.
18 More than half of those days were spent in the
19 intensive care unit unable to speak, on a respirator,
20 and totally paralyzed. That hallowing experience led
21 me to help found the GBS Syndrome Foundation
22 International, a support group and a research

1 organization which now has 35,000 former GBS patients.
2 On October 28 of this year in Philadelphia, we will
3 celebrate our 30th anniversary.
4 I pledge to you today that GPhA and I will
5 collaborate with all stakeholders in this room, but I
6 can assure that the organizations here representing
7 patients will always have a special advocate in Ralph
8 Neas and GPhA.
9 I want to begin my presentation by sharing
10 some important information about the generic
11 prescription drug industry. As we discuss the issue of
12 drugs shortages and examine potential solutions, I
13 think it's very helpful to have a better understanding
14 of the generic industry and the pharmaceutical supply
15 chain. Then I want to present a brief overview from
16 our perspective of the drug shortage crisis including
17 some of the major facts about shortages. We'll look at
18 a couple of the contributors to shortages and drug
19 supplies and proffer some proposed solutions. Finally,
20 I'll mention a few of the opportunities as well as new
21 responsibilities that we believe exist for
22 manufacturers.

1 Number 1, it is important to realize that
2 pharmaceutical manufacturing whether brand-named drugs
3 and generic is a global business. As we will discuss
4 shortly, the global nature of the drug supply chain
5 including active pharmaceutical ingredients, inactive
6 ingredients, drug delivery devices, and finished-dose
7 products, often add challenges to meeting market
8 demand.
9 For instance, while there may be two or even
10 three different foreign suppliers of a particular
11 active ingredient, no drug, brand or generic, can be
12 sold in the United States unless all active ingredients
13 in the drug are approved by the FDA.
14 In addition, generic finished-dose products
15 whether tablet, capsule, ointment, injectable, or other
16 dosage form must have passed the rigorous and exacting
17 FDA approval process to show that they are absolutely
18 equivalent to the brand-named drugs and safety
19 performance characteristics, intended use, and quality.
20 Moreover, FDA's CGMP regulations, current good
21 manufacturing practices, apply equally to generic
22 manufacturers and brand drug manufacturers.

1 On a separate point, it is often mentioned
2 that the majority of drugs on the drug shortage list
3 are generic. I will address that further in a moment,
4 but it's important to remember of the 4 billion
5 prescriptions that would be dispensed in the United
6 States this year more than 3 billion will be filled
7 with generic drugs. It is no wonder that nine of the
8 world's largest drug manufacturers by volume of
9 medicines manufactured are generic companies. And I
10 should note that GPhA member companies manufacture the
11 drugs that will fill nearly 90 percent of those 3
12 billion prescriptions.
13 And finally, while it is known that generics
14 cost less, a study released just last week based on
15 data from IMSL shows that the use of generic
16 prescription drugs saved the United States healthcare
17 system $937 billion over the past decade, $158 billion
18 in 2010 alone. That is an astounding $3 billion every
19 week of the year.
20 Again the background of these numbers and
21 this market data, there can be no question that generic
22 manufacturers are in the business of supplying medicine

1 and assuring that consumers and patients have access to
2 the drugs they need. That's our business model: To
3 make medicines available and affordable to all. But we
4 are not blind to the regrettable reality that there are
5 time when for various reasons certain drugs are in
6 short supply. Whether because of unexpected demand,
7 regulatory issues, or the unavailability of raw
8 materials, shortages unfortunately happen.
9 I can state unequivocally that we are acutely
10 aware of the distress caused to patients, families, and
11 clinicians by the shortage of medically-necessary
12 drugs. The generic industry is devoted to working with
13 all stakeholders to minimize current shortages and
14 mitigate factors that could contribute to future
15 shortages.
16 And despite the fact that the issue is
17 complex and is a multi-stakeholder issue, the generic
18 industry is resolute in its commitment to be part of
19 the solution to dramatically decrease drug shortages.
20 Of course, we are hearing today a lack of supply of a
21 medically-necessary drug can be devastating even if it
22 impacts only one patient.

1 As we work together to examine solutions to
2 the shortages crisis, it is critical that we understand
3 that the answer to those shortage issues transcends the
4 generic industry. In truth, the solution provides
5 opportunity for all components of the supply and
6 provider network to cooperate in addressing the
7 problem. That includes brand manufacturers, active
8 ingredients suppliers, component suppliers, wholesalers
9 and distributors, group purchasing organizations,
10 healthcare providers, the FDA, DEA, and other
11 Government agencies.
12 Another factor affecting the shortage issue
13 is that a significant percent of the medicines on the
14 shortage list are injectable products that require
15 specialized manufacturing facilities. As a result,
16 there is often finite production capacity.
17 Injectables are products with high risking
18 manufacturing challenges due to the sterility
19 requirements and other necessary regulations. Even the
20 slightest deviation from the manufacturing requirements
21 can lead to shutting down a production line.
22 One other aspect of this issue that warrants

1 a mention is that many of the medicines in short supply
2 are sold only in the generic form. The original brand
3 version no longer is on the market even though the
4 brand in most cases still is approved by the FDA. In
5 other words, for many shortage drugs, the original
6 brand for whatever reason has been discontinued leaving
7 the generic as the only supplier.
8 My point in mentioning this is not to
9 question why brand companies leave the market after
10 generic competition enter; rather, it is only to note
11 that while generic manufacturers frequently are singled
12 out as the cause of shortages the brand manufacturers
13 in many cases no longer make the product in short
14 supply.
15 Before looking at some specific causes and
16 proposed solutions, here are several facts that we
17 believe need to be kept in mind. First, contrary to
18 what sometime is reported in the press, generic
19 manufacturers do not deliberately reduce supply of
20 necessary medicines in order to push up the price of
21 these products. As I mentioned earlier, our member
22 companies are in the business of manufacturing and

1 providing medicines. There is more to be gained from
2 selling products than from not selling products.
3 Additionally, some believe that consolidation
4 within the industry has been a significant contributor
5 to drug shortages. However, it appears from available
6 evidence that consolidation has little impact on
7 shortages.
8 Also, generic manufacturers strong oppose the
9 action of opportunistic gray market distributors, those
10 distributors who purchase supplies and then resell them
11 at much higher prices.
12 Another fact is that drug shortages typically
13 are not caused by a generic manufacturer's decision to
14 voluntary discontinue supply the product. As noted
15 previously, generic manufacturers generally do not
16 voluntarily stop making and supplying medically-
17 necessary supplies and products.
18 Lastly, it is important to remember when
19 considering solutions to this important issue that any
20 supply shortage from one company could create
21 challenges for other companies to meet additional
22 demands, particularly where special facilities are

1 required such as in oncology.
2 Now I want to focus on a couple of key causes
3 for drug shortages and suggest some potential
4 solutions. Our members are committed to producing safe
5 and effective generic drugs. Nevertheless, despite the
6 best efforts of manufacturers, there will occasionally
7 be instances where the FDA is forced to act on
8 potential CGMP violations. As a result of these
9 compliance actions, many medically-necessary drugs may
10 be soon in short supply.
11 Indeed, 50 percent of all drug shortages are
12 caused by compliance action. If there is a compliance
13 issue that could be addressed in relatively short order
14 so that a medically-necessary drug might remain in
15 production, FDA should work manufacturers to ensure
16 that happens. Moreover, FDA should consider strongly
17 options to maintain supplies of medically-necessary
18 drugs while working with firms to correct CGMP issues.
19 In many instances, it is not feasible for
20 companies to submit an application for secondary active
21 pharmaceutical ingredient, API, or other raw materials
22 supplier. Therefore, when a manufacturer confronts a

1 delay in the arrival of raw material, API, production
2 of critically-necessary drugs can be halted for
3 significant amounts of time.
4 On the other hand, some other regulatory
5 authorities in Europe and elsewhere can approve
6 supplemental API suppliers in 30 day. Similarly, a
7 prior approval settlement can take multiple years in
8 the United States, while similar changes are
9 accomplished in Europe and elsewhere in much shorter
10 timeframe.
11 An additional source of drug shortages has
12 come via controlled substances. Quite simply, FDA and
13 the Department of Justice must respond to potential
14 shortages of DEA-regulated products in a more expedited
15 fashion.
16 As you have heard today, many stakeholders
17 believe a notification system as outlined in
18 legislation introduced in both houses of Congress will
19 help reduce and prevent drug shortages. While GPhA and
20 its members do not oppose a notification system on its
21 face, it is important that such a process be further
22 refined and formalized to include manufacturers, the

1 FDA, and other stakeholders through the supply chain.
2 Careful consideration must be also taken to ensure such
3 at notification system does not create additional gray
4 markets or otherwise cause further supply disruptions.
5 As an industry, our goal is to work with the
6 FDA and all stakeholders to turn these proposed ideas
7 into real and workable solutions. Although some
8 solutions will require more time than others to
9 implement, there are some actions we can begin taking
10 in the near term to address the issue.
11 First, we want to work with the FDA to
12 formalize the process not only for manufacturers but
13 also for others to proactively report drug shortages to
14 the FDA's Drug Shortage staff. Many generic
15 manufacturers now do this voluntarily, but a formal,
16 structured process for reporting shortages will both
17 the agency and industry to mitigate the damage a
18 shortage can cause. We believe such a process could be
19 instituted in a manner that would maintain
20 confidentiality of a company's proprietary information
21 and market data.
22 Additionally, the past few years have taught

1 us that we must be creative and look at every
2 opportunity to mitigate drug shortages. Industry and
3 the FDA should reexamine current policies and
4 procedures to identify ways to predict potential market
5 shortages as early as possible and to design a
6 collaborative process that will speed needed approval
7 or global inspection before we experience shortages. By
8 identifying triggers that would warrant priority
9 reviews in inspections to address shortages, we could
10 develop processes that could avert the unavailability
11 of medically-necessary drugs.
12 Second, we want to work with FDA to proactive
13 develop a defined and updated list of all medically-
14 necessary drugs. Currently, FDA only does this on a
15 case-by-case basis, and its review is reactive. We
16 already have asked FDA to proactively define or
17 determine which drugs they deem medically-necessary,
18 and we hope the agency will provide this soon.
19 Third, where possible, we want to maximize
20 capacity and redundancies for medically-necessary
21 drugs. Generic pharmaceuticals are currently working
22 FDA to prioritize the supply of the medically-necessary

1 drugs, and as we move forward, we can focus on
2 maximizing capacity and redundancies for needed drugs
3 that are in short supply.
4 And fourth, in partnership with the FDA, we
5 want to develop better and more successful strategies
6 to assure the highest quality while concurrently
7 aggressively addressing any manufacturing issues.
8 We do believe that despite how hard the FDA
9 does all of its work in an extraordinary manner there
10 must be additional resources, and I see Susan getting
11 closer and closer to me, so I will cut off here right
12 about now.
13 I do want to just end by saying that while
14 many factors can cause drug shortages the most serious
15 shortages are often unexpected. We must work together
16 to find solutions that focus both on current shortages
17 and on minimizing the risk of future shortages.
18 Finally, the FDA and industry should
19 reexamine current policies regarding identifying and
20 addressing potential drug shortage issues, and we look
21 forward to beginning that process immediately.
22 On behalf of us and all of our members, we

1 want to thank the FDA for its commitment to addressing
2 the issue. Very importantly, let me assure patients
3 and providers that we are working hard to solve this
4 problem of drug shortages. And I want to paraphrase
5 the two most memorable phrases I heard this morning. I
6 think it was Dr. Pricken (ph) and Dr. Lichtenfeld, and
7 let us underscore one more time before we leave today
8 that the drug shortage crisis compels unprecedented,
9 multi-stakeholder collaboration, communication, and
10 consensus. And as Dr. Lichtenfeld said, now.
11 I'm deeply grateful for being here today.
12 Thank you.
13 MS. WINCKLER: Thank you, Ralph. And welcome
14 to the Food and Drug law community. I can imagine that
15 you will be present at future public meetings as well.
16 We have one more speaker, and then we'll get
17 into the panel discussion here with the folks in
18 industry. Making his way to the podium is Thomas
19 Moore, who is president of Hospira, and I will turn it
20 over to Thomas.
21 MR. MOORE: Thank you very much. Good
22 afternoon, everyone. I'm Thomas Moore, president of

1 the U.S. operations for Hospira, and it's an honor to
2 be here today. First of all, I'd like to commend the
3 FDA for holding this workshop and inviting us to
4 participate as well.
5 As the world's largest makers of generic
6 injectable pharmaceutical, Hospira shares out customers
7 and the public's concern about shortages, and we regret
8 that some of our products have been among those in
9 short supply.
10 As we've discussed today, drug shortages are
11 a multi-stakeholder issue, and addressing the broader
12 situation requires a collective effort. We support the
13 initiatives outlined today, and we also support the
14 drug shortage legislation. We've already taken some of
15 the steps recommended by the bill; look forward to
16 working with GPhA and other industry members, patient
17 groups, Congress, and the FDA to put those
18 recommendations in place in an effort to prevent and
19 lessen the impact of future drug shortages. We share a
20 collective responsibility as an industry to make sure
21 that patients obtain the medication they need.
22 Ralph did an excellent job explaining the

1 causes of drug shortage and also dispelling some of the
2 myths. So instead of reiterating his earlier comments,
3 I'd like to spend a brief time discussing the step that
4 Hospira has taken and the rest of the industry as well
5 and continues to take to meet the needs of patients and
6 also clinicians that serve them.
7 We have a three-pronged approach to
8 addressing drug shortages: We listen, we communicate,
9 and we act. We actively meet with customers and listen
10 to customer concerns to ensure our organization is
11 engaged in the very critical issues. We have regular
12 conversation with the FDA as well to find out where the
13 most serious market needs exist.
14 By listening to our stakeholders, we know
15 that one of the biggest challenges customers,
16 clinicians, and regulators face is communications. So
17 we've improved how we communicated. We post important
18 information on supply updates on our Web site. We
19 recently added updates on supply to every product that
20 we make, and we include product availability
21 information the same as we communicate to the FDA's
22 Office of Drug Shortage and other stakeholders.

1 Although reporting drug shortages to the FDA
2 to is not mandatory, Hospira takes such reporting very
3 seriously, and we're in communication with the FDA
4 Office of Drug Shortage at least once a week, making
5 sure the agency has comprehensive information on the
6 status of our products' availability.
7 As specific issues arise, we are in
8 communication as often as required, sometimes daily or
9 even multiple times daily. And when product shortages
10 occur, we act. Earlier this year, there was a product
11 shortage of the critical cancer drug cytarabine. We've
12 heard a lot about that today. Patients were having
13 trouble obtaining the medication due to industry-wide
14 shortages. I can tell you that the industry along with
15 Hospira quickly addressed some quality issues
16 associated with production of the drug and worked
17 tirelessly to try and bring as much drug to the market
18 as quickly as possible.
19 At the FDA's request, we're bring back to
20 market an electrolyte product we've also heard about
21 today, an old product, a simple product, and
22 everybody's scratching their head why this product

1 should be in short supply, and that's potassium
2 phosphate.
3 We're also taking action to address shortages
4 by increasing capacity at existing facilities, building
5 additional capacity, and literally investing hundreds
6 of millions of dollars to improve our manufacturing
7 plants.
8 We recently announced that we're constructing
9 a more than 1 million square foot sterile injectable
10 manufacturing facility that will provide important
11 backup capabilities in the event that we experience
12 production problems at our other plants. And of
13 course, this new facility will free up capacity in our
14 current manufacturing footprint and allow us to
15 optimize and modernize some plants in our existing
16 manufacturing base.
17 Additionally, we have acted to increase
18 inventory, and this is not a long-term solution to the
19 problem, but sometimes it's a short-term solution that
20 can help mitigate further shortages.
21 We've been making safe and effective
22 injectable drugs for more than 70 years and are

1 absolutely committed to working with the FDA to
2 maintain the levels of operational excellence that made
3 us the largest generic injectable drug company in the
4 world.
5 Before I finish, I want to reiterate what I
6 consider to be a couple of myths regarding the root
7 causes of drug shortages and also one of the myths
8 around what we've heard a lot about today, and that's
9 gray market distribution. So let me take the second
10 one first here.
11 There are those that believe in some fashion
12 or other the industry is profiteering from gray market
13 distribution. That is absolutely not true, and in fact
14 at Hospira we abhor those activities, and I can tell
15 you that in the last 18 months we have discontinued
16 relations with a dozen different secondary distributors
17 who we found were operating in the gray market. So we
18 closely monitor this activity today, and as I say, we
19 do not support this price gouging activity that's
20 rampant in the industry taking advantage of patients
21 and providers.
22 The second item I'd like to address, which I

1 consider to be a myth, is one that Ralph also mentioned
2 at least with respect to the generic injectable segment
3 in the United States, and that is the notion of
4 consolidation. So there has been significant
5 consolidation across the vast pharmaceutical industry
6 around the world. We've all seen that in recent years.
7 But in the generic injectable segment, I can't think of
8 a situation where consolidation is a root cause of a
9 drug shortage that we have today.
10 Now I'm not saying that I have complete
11 knowledge of this, but I believe this to be true. The
12 largest three acquisitions that have occurred in the
13 generic injectables segment in the last five years, two
14 of which were executed by Hospira, both of those
15 acquisitions that we made we actually added additional
16 capacity to those facilities. And the third
17 acquisition that occurred in this space was Fresenius
18 Kabi's acquisition of APP, who also is adding
19 additional capacity in this space. So I don't believe
20 consolidation with respect to the generic
21 pharmaceutical industry has been a root cause.
22 Like other companies in our industry, we're

1 deeply aware of the products' impacts on patients'
2 lives. We're dedicated to continuing to listen,
3 communicate, and act in order to ensure that patients
4 can always obtain the critical medical products they
5 need, and we look forward to collaborating with the
6 industry and regulators to bring about solutions.
7 And before I leave the podium, I want to
8 publicly acknowledge the fine work of the Office of
9 Drug Shortage, and I have to tell you that I can point
10 to a number of examples where they have actually helped
11 industry prevent shortages. Their role in managing and
12 preventing drug shortages is manifestly important, and
13 it's equally manifestly important that we continue to
14 support them. Thank you.
15 MS. WINCKLER: We'll do the panel discussion
16 with the manufacturers of products based on our earlier
17 discussion we know in many situations are lifesaving.
18 To talk with that, we've also reached then the point
19 where we're talking with the folks and hearing from the
20 folks who are directly regulated by FDA, and we haven't
21 gotten to that point until here. This is where FDA has
22 the most regulatory authority and the most interaction.

1 To help with our discussion, we're adding
2 four more experts, and they are all the way across the
3 room from me, but we have Maya Birmingham, who's senior
4 assistant general counsel with PhRMA. Next to Maya is
5 David Gaugh, who's vice president and general manager
6 with Bedford Pharmaceuticals. You've heard from Ralph
7 Neas, and I know we'll hear from him in this discussion
8 as well. Then we have Jonathan Kafer, vice president
9 for sales and marketing with Teva Health Systems. Then
10 Scott Meacham with APP Pharmaceuticals, executive vice
11 president and chief clinical officer. And then
12 rounding out that part of the panel with Thomas Moore,
13 who you just heard from, from Hospira.
14 So to the whole panel -- and we will give the
15 folks other than Ralph and Thomas the first opportunity
16 to respond -- if you look now at the structure of the
17 solutions that have be suggested, looking at those
18 solutions that are built on preventing shortages versus
19 those solutions that look at mitigating shortages, the
20 shortage prevention Ralph and Thomas added some things
21 that are very helpful including looking at making sure
22 that we have a stable market with market players who

1 are committed to meeting the regulatory requirements.
2 We heard from some of the purchasers about longer term
3 contracts; heard again this theme throughout the day
4 about improving communications so that shortages can be
5 prevented.
6 On the mitigation side, communications again
7 came up: What more can we do in communications about
8 fair allocation. And then some best practices when
9 there are shortages. In both prevention and
10 mitigation, changes in the regulatory process to
11 expedite and address situations.
12 Maya and the rest of the panel, what might
13 you added to that list of solutions from the
14 manufacturing sector? You've faced these challenges
15 those of you are manufacturers and the associations
16 hear about them. What other solutions would you throw
17 into the mix?
18 MS. BIRMINGHAM: Let me start first and
19 introduce myself again. I'm Maya Birmingham. I wanted
20 to sort of ground us all again. We've heard from many
21 different stakeholders today, and I was touched in
22 particular by the patients who came to us and told us

1 their stories, and one thing that struck me was we are
2 all patients at one time or another, and certainly as a
3 personal matter, I think the drug shortages are very
4 important to me. I have experienced drug shortages,
5 and certainly our members are committed to solving drug
6 shortages.
7 The one thing that I think we keep hearing
8 over and over again is to have a continued commitment
9 to looking at the root causes of drug shortages and
10 having a common vocabulary. I think one of the things
11 that strikes is we're all in the room to try and solve
12 this problem, and we're all trying to grasp what the
13 issues are. And I think it's very important to have
14 that common vocabulary.
15 MR. KAFER: This is Jon Kafer. I'm with
16 Teva. Thank you very much for the opportunity to be
17 here as well.
18 I think there's a couple of things I'd have
19 to point out. First of all, through some of the
20 earlier presentations this morning we have heard, and
21 certainly understanding, if you could just make it we
22 wouldn't have this problem. Well, believe me, we would

1 like to do nothing more than just make it.
2 Also, we've had two different reports that
3 have qualified a lot of the shortage; about 50 percent
4 have been related to manufacturing-related issues. I
5 would not dispute that.
6 I thought it was interesting this morning too
7 there was a comment made by one of the panelist that
8 said whether you get a leak in a facility. Well, trust
9 me, if you get a pin-hole leak in a water facility --
10 the water system that goes to your facility, the timing
11 to remediate that as well as remediate those room in
12 which you're able to go back into production does take
13 time.
14 What I think we need to focus on is how do we
15 focus on accelerating the recovery. We have had
16 various disruptions in supply through many facilities
17 that are at varying stages of recovery and production,
18 and quickly we are working to get to historical
19 production volumes.
20 What we have seen and what's been documented
21 by the great work by Val, Emily, Jouhayna, and the
22 whole team at Drug Shortage is 99 drug shortage events

1 were eliminated. What we're doing right now work. How
2 do we apply that process up the food chain, if you
3 will, up the process why we continue to do that. So
4 the lessons learned as we work through the crisis is
5 we're collaborating, we're working together.
6 I don't take the opinion that it's solely
7 FDA's responsibility to communicate all of this. Their
8 information is only as good as what we give them as a
9 manufacturing community. And I can speak for the four
10 of us up here that we are working very closely with
11 them. We need to pull the distributors more closely,
12 and we need to pull in the institutions and clinics
13 more closely as well to have that complete stakeholder
14 continuum in that conversation.
15 So I think what we have done as a result of
16 the crisis is a tremendous foundation from which we
17 need to build.
18 MR. MEACHAM: Scott Meacham with APP, but I
19 do want to correct one thing. I'm not the chief
20 clinical officer. I'm the chief commercial officer.
21 In case I get asked a difficult question later, I want
22 to clarify that now.

1 (Laughter)

2 MR. SCOTT MEACHAM: The one I --

3 MS. WINCKLER: You've identified the error in

4 my notes. Thank you.

5 MR. SCOTT MEACHAM: The thing I would add to

6 Jon's comments and what can be done and some of the

7 solutions I think it comes down largely to capacity and

8 redundancy and your ability to react. And we all

9 operate in a very competitive environment, particularly

10 the generic injectable environment. We are not sitting

11 around with excess capacity typically. We run our

12 plants and our manufacturing facilities as efficiently

13 as we can to provide products to you at the lowest

14 price possible. So we need to have redundancies. We

15 need to have redundancy in our API suppliers, our

16 manufacturing sites. And that's not always easy to do.

17 One of the things -- and Tom commented on it

18 in his remarks -- when APP was acquired by Fresenius

19 Kabi, if it wasn't for that acquisition, we would not

20 have been able to step up to the demand of propofol in

21 the market. That product is largely manufactured by

22 Fresenius Kabi in Europe, and it wasn't without their

1 capability that we could do that, and we make that
2 product in two separate facilities. So again, the
3 redundancy of having the capability of making these
4 critical medications in multiple locations I think is
5 important.
6 As we look to the drug shortage, when they
7 call us, we look around at all of our manufacturing
8 facilities and see where can we make this product. And
9 to me, that's a big part of the problem in not having
10 the excess capacity.
11 MS. WINCKLER: David, would you like to weigh
12 in?
13 MR. DAVID GAUGH: I will. David Gaugh from
14 Bedford Laboratories. And actually it'll be more of
15 repeat than anything of what my colleagues have just
16 stated.
17 So capacity is a major issue. That's
18 definitely true. And we as the industry are doing
19 everything we can to increase that capacity. I think
20 one thing I would like you to understand and to help
21 you understand. As Tom mentioned, they were building a
22 million square foot facility. We're all expanding our

1 facilities, but those facility expansions take a
2 significant period of time. So from the day you make
3 the plan, break the ground, and then have the FDA
4 approve your facility for production and then begin
5 moving products in there, which is not the next day --
6 it starts the next day, but it migrates over a period
7 of time -- can take up to five to seven years to
8 accomplish. So, as the gentleman said before, it is
9 not a quick fix.
10 The one thing I will say and the one word,
11 the watch word I'd like us all to focus very hard on,
12 and I mean all of us from stakeholders but especially
13 us and the FDA, is collaboration. I've seen a great
14 improvement, and I don't mean that to be a negative
15 sound, but a great improvement and increase in
16 collaboration between the industry and the FDA, and we
17 greatly appreciate that collaboration. To be able to
18 work together and work collectively for a common goal
19 has been very successful for us. So thank you very
20 much for that.
21 CAPT JENSEN: We've heard a lot of talk today
22 about many different solutions. Some of those

1 solutions are things that FDA can do, and some of them
2 have to do with other regulatory agencies at the
3 Federal and state level. Who are the agencies that you
4 interact with -- and I'll use the DEA as an example
5 when it came to controlled substances and the need to
6 look at the API quotas -- are there others regulators
7 and other parts of the problem where we're talked about
8 solutions today but perhaps haven't said who it is who
9 should implement those solutions?
10 I'm looking here for those -- what is the
11 highest priority for FDA? And then who are the highest
12 priority regulators outside of FDA that can help us
13 solve this problem of preventing shortages and
14 mitigating them? Any thoughts? Thomas, you're first.
15 MR. MOORE: Sure. Thank you. Well, first of
16 all, in terms of cooperation with the FDA. As I
17 mentioned before, I will tell you that I don't think
18 it's ever been better. Doesn't mean it couldn't
19 improve. And as I mentioned in my comments, I've seen
20 tangible example of working with the Office of Drug
21 Shortages that have actually resulted in preventing
22 future drug shortages.

1 But I think there are a couple of areas where
2 we could see sort of better interaction with the agency
3 in terms of addressing a drug shortage and enabling the
4 industry to perhaps more quickly qualify new API
5 suppliers, qualify new manufacturing lines, or even
6 with the assistance of moving products from one
7 manufacturing plant to another in the event that there
8 is a manufacturing problem at an existing facility. I
9 think those are areas that we have starting to see
10 improvement there. But I think it's also areas that we
11 could concentrate more on and see further improvement
12 going forward.
13 With respect to the DEA, I would tell you and
14 a number of folks have commented on Schedule II drugs
15 quotas, that has been an issue. I can't say that I've
16 seen as much progress in that area although there has
17 been some. So I think that's a dialogue that we need
18 to continue to have with the Department of Justice and
19 more quickly adjusting DEA quotas as a results of
20 demand and also manufacturing dynamic; manufacturing
21 dynamics being perhaps one company has faced a problem
22 which prohibits them or is preventing them from

1 providing a supply of products in the marketplace, and
2 that volume needs have some uptake by another
3 manufacturer. It can only be done so by quick action
4 with the DEA to improve quotas. So, not to be
5 redundant there, but I just wanted to mention because
6 that's an area that I think we definitely could see
7 better improvement.
8 MS. WINCKLER: And I don't think this was
9 explained earlier. On the DEA quota for APIs for
10 Schedule II controlled substances, is that set for the
11 API as a whole in an industry wide or per manufacturer?
12 MR. MOORE: The quotas are applied on a per-
13 manufacturer basis, but I believe the DEA does
14 recalculations in terms of what they consider to be
15 total market demand.
16 As I say, what's not taken into consideration
17 is maybe dynamics that occur between manufacturers; in
18 other word, perhaps one company being prevented in some
19 fashion or other, a quality problem or manufacturing
20 issue, from fulfilling that quota, and it might be
21 taken up by another.
22 The other thing I would say is that there has

1 been some significant increases in select Schedule II
2 narcotic products in terms of market growth in recent
3 year, and I point to hydromorphone. And the growth of
4 hydromorphone use in this country has significantly
5 grown in the last five year to some extent at the
6 expense of morphine and also meperidine. And my sense
7 is perhaps the agency -- the agency being the Drug
8 Enforcement Agency -- has not quite kept up with the
9 fundamental demand in the marketplace in terms of
10 growth for that molecule.
11 MS. WINCKLER: Thoughts from other panelists
12 on those questions about the most important piece for
13 FDA and then other agencies that may have a role in
14 helping us develop solutions.
15 MR. KAFER: Just to expand a little -- this
16 is Jon Kafer with Teva. Just to expand a little bit on
17 the point around lessons learned and to follow up on
18 Thomas's. We have seen -- when we're making updates
19 and changes to products, processes, and facilities,
20 those are often generating pretty extensive reviews as
21 required. Given the criticality of some of these
22 products we're been able to work, quarterbacked by the

1 Drug Shortage group in collaboration with all the
2 branches, to get an expedited review done in a matter
3 of months. We've seen that. We've all have
4 experienced that. And that that means is that's been
5 allowing us to accelerate that product back to market.
6 Now as we've all discussed, we at Teva as
7 well are completing a complete redundancy plan for our
8 critical products where we're qualifying other sites.
9 We're also building a brand new facility, and we're
10 also creating redundancies. It's going to be a lot of
11 activity that's going to be coming in, many of which
12 are designed to be on those critical products, so we
13 would hope we continue to work with expedited review
14 and then work toward getting it into more of a standard
15 flow; because as we realized, in this process a lot of
16 the critical shortages are unanticipated.
17 So we all work with and we identify and check
18 with and provide information to Val and her team on
19 what we know at this point, but it can change on
20 Monday, and that's very difficult to predict. So as a
21 standard flow is adopting what we've been able to do of
22 late would make a big impact.

1 MS. WINCKLER: Thank you. Ralph.
2 MR. NEAS: Susan, may I ask a question in
3 response to your question. As people around could well
4 imagine, the last 10 and half days or so have be like
5 drinking water from a fire hose from the new CEO. One
6 thing that I've been struck by all day is the amount of
7 attention spent on the gray market, the gray marketers,
8 and you were asking us about enforcement and which
9 agencies. It's still not clear to me with respect to
10 the gray market who has principal enforcement
11 responsibility? How does that work? It seems like
12 such an obvious thing that we all have to talk about
13 and collaboration about. But who do we talk to and who
14 has the enforcement responsibility?
15 DR. BERNSTEIN: Everyone's looking at me
16 here.
17 (Laughter)
18 MS. WINCKLER: I was going to say, Ilisa,
19 everyone's turned toward you so...
20 MS. BERNSTEIN: Okay. All right. Hi, Ilisa
21 Bernstein, Office of Compliance. The gray market is
22 gray for a reason. It isn't one entity that has

1 oversight over the gray market. There's states
2 involved. There's Federal Government is involved.
3 Various DEA is involved when it's a controlled
4 substance. We at FDA have worked a lot with hospitals
5 and hospital pharmacists and others who get these kinds
6 of blast faxes when you get these offers and ask that
7 this information come to FDA so that we could actually
8 look -- because to us, those are red flags that
9 something fishy is going on here; because as we said
10 earlier, if these distributors or these entities can
11 actually find drug when nobody else can, then something
12 is up.
13 But it's kind of a partnership over various
14 parts of the Federal Government and state government
15 and law enforcement.
16 MS. WINCKLER: So are you -- was the question
17 who do you report it to? Or who do we go? Who do we
18 work with? What was the questions? If it was all of
19 the above?
20 MR. NEAS: Who has ultimate responsibility to
21 make sure that if it is happened that there is
22 enforcement?

1 MS. WINCKLER: I think state boards of
2 pharmacy have the principal role in licensing wholesale
3 distributors, and I think the challenge that we see
4 created here by Dr. Bernstein's explanation of the gray
5 market is that there are different rules at the state
6 level and the different capabilities of those
7 regulatory agencies.
8 But I asked the question to remind us that,
9 as was pointed out earlier, no one has presented FDA
10 with the hammer of Thor to be able to fix the shortage
11 problem by itself, and there are other agencies that
12 will play in the solution. Bona, you had a question?
13 MS. BENJAMIN: Yes. On behalf of ASHP and
14 its members, this is a question that we've been kind of
15 wondering about for quite a while. Because, as I said,
16 when I get the green light from Val that a company is
17 back up to full capacity and they have inventory even
18 ready to go out and then I'm hearing from my members
19 that they can't get the drug from anywhere, I wonder
20 what happens between the manufacturer and the end user?
21 I don't think manufacturers are telling FDA the wrong
22 information when they say, "Okay, we're back up to

1 capacity. We've resolved everything."
2 By the same token, the pharmacists are still
3 reporting that they've tried wholesalers, they've tried
4 other places, and they just are reporting a lack of
5 product at the end user level. So there's a
6 discrepancy there that's very curious, and that's why I
7 made a comment earlier about the integrity of the
8 supply chain.
9 I heard Hospira talk about how they control
10 who they sell to. They want sell to -- and correct me
11 if I'm wrong -- entities that sell to these secondary -
12 - maybe secondary distributors is not the right word --
13 they sell to authorized distributors of record only. We
14 think that's that great, but somehow product is leaking
15 into the gray market during some point in distribution
16 chain. I don't think the manufacturers are selling to
17 these people.
18 That's a big question for us too. I'd love
19 to hear some answers or some speculations on why that's
20 the cases.
21 MR. GAUGH: David Gaugh from Bedford
22 Laboratories. Bona, without having specifics on the

1 product you're talking about, I don't know that I can
2 specifically answer the whys, but some thought process
3 into that. So once we would call the Drug Shortage
4 group and tell them that we're back to full
5 manufacturing, you have to understand the pipeline is a
6 significant pipeline to fill. We heard from one of the
7 major wholesalers, but there are two others, and then
8 there are probably eight or nine subwholesalers, not
9 secondary but just subwholesalers. And to fill that
10 pipeline takes a significant period of time.
11 So for a while you release a product, it goes
12 on allocation by the manufacturer, and then it goes on
13 allocation by the distributor, the wholesaler groups,
14 and then gets into the pipeline. So it can take up to
15 two to three months before the pipeline gets filled. So
16 I think that would probably be the most logical answer
17 to your question. But during that time, we have it,
18 and we sell it directly to the customers who need it
19 and request it.
20 MS. WINCKLER: Scott.
21 MR. MEACHAM: And Bona, I would just add that
22 similar to what Dave commented on and Tom, we don't

1 know how it gets there either. We're as perplexed as
2 the customers are, the healthcare professionals are.
3 One thing I do want to comment on though.
4 When we do release products and we communicate to Drug
5 Shortage that we are releasing, as Dave indicated, it
6 takes a few day to get there. It takes a few days to
7 get into the channel. But I encourage people to call
8 us at least in the case of APP directly. If we've
9 released products, we typically have retained some
10 products as well. And so in an emergency situation,
11 we'll do what we can get it out.
12 One of the presenters this morning commented
13 on cytarabine as an example. We have cytarabine on
14 free flow. I'm not sure why there appears to be a
15 shortage of cytarabine in the market, and I believe
16 it's on free flow by some of our other suppliers in the
17 market. So I encourage you that when you run into that
18 with a gray marketer, please pick up the phone, and
19 we'll do what we can to try to assist.
20 MS. BENJAMIN: Anybody out there having
21 trouble getting cytarabine still? Can you raise your
22 hand?

1 Because we had heard reports that cytarabine
2 is unavailable in some places.
3 MS. WINCKLER: Dr. van Eeckhout.
4 MR. van EECKHOUT: One of the issues about
5 the gray market. In an earlier conversation we were
6 talking about the state boards of pharmacy. I would
7 have to tell you that I don't think the state board of
8 pharmacy does a very good job of licensing people. I
9 think they just go ahead and take the money and turn a
10 blind eye to whatever they're doing.
11 We did an RFP about four or five years ago
12 for a group of blood products, and when we did this
13 RFP, we got 12 distributors came in and said that they
14 could do all the stuff. When we went back to the
15 manufacturer and asked who are the qualified
16 distributors, seven of them disappeared immediately
17 because they were not qualified.
18 I think that the issue is, unfortunately to a
19 certain degree, incumbent on you if you're selling it
20 directly to find out if these people are legitimate or
21 not. I think there is a real issue in the market just
22 because they have a wholesaler license or a reseller

1 license or whatever it is or whatever state does it, it
2 doesn't necessarily legitimize them as an actual
3 provider.
4 And in fact what we were talking about is
5 probably some sort of chain of custody issue that
6 really guarantees the supply chain from the
7 manufacturer to the point of administration of to
8 patient. And I know that's difficult, but I think
9 that's probably where we're going to end up. Or we're
10 going to have to have some significant legislation to
11 eradicate the gray marketers.
12 MR. KAFER: To expand a little bit on David's
13 point. The amount of direct customers we ship to is
14 very, very small, and we're talking about 15 or less,
15 to David's point; and Anita, I believe you have 34, 35
16 full-fledged HDMA members. And keep in mind that
17 between the big three wholesalers and their specialty
18 distribution arms that are specific to oncology,
19 they're responsible for getting to 90-plus percent of
20 the marketplace.
21 So we do very tightly control and can show
22 exactly where it left our door to where it was

1 received. And it's not a big list.
2 MR. GAUGH: And I would add to that, from a
3 gray market perspective, remember this is
4 entrepreneurial America, and so they'll get it from
5 every avenue they can get it from. I can tell you 100
6 percent to every person at this table we do not sell
7 directly to the gray markets. If we find out one is
8 there, we immediately pull it. But they are very
9 entrepreneurial in getting it from the major
10 wholesalers for example. They're very entrepreneurial
11 in calling the hospitals themselves to say, "Do you
12 have a box of 10 that I can buy from you?" Not
13 identifying who they are, and they get it, and they'll
14 sit on it for a few days, and then turn around and sell
15 it back.
16 So it's a process -- it's back to Ralph's
17 question of who could control these companies, and I
18 think in entrepreneurial America, it's very hard to do,
19 but that is an area we need to look into and quickly.
20 MS. WINCKLER: Michael, one more comment, and
21 then we'll do a wrap-up of the panel.
22 MR. MONE: Thank you, Susan. In full

1 disclosure, I have to tell you that I actually sit on a
2 state board of pharmacy, so I think that it's fair that
3 you know the bias that about to come, and most of my
4 history has been with state board of pharmacy.
5 Susan is actually quite correct. It varies
6 between the states as to their ability to enforce the
7 statutes that they're faced with. I will also tell you
8 that the statutes themselves vary quite dramatically as
9 far as what the requirements are for being licensed as
10 a wholesaler in each individual state.
11 So there is some tightening to do in that
12 particular area, and I think it's probably appropriate
13 that NADP be engaged in the process as well.
14 I will also point out that just as the
15 manufacturers do their due diligence on the people to
16 whom they sell, us, as pharmaceutical distributors and
17 business partners, speaking for CardinalHealth, we do
18 the same thing with the customers that we actually
19 engage in selling to as well. Our due diligence is the
20 same type of due diligence to make sure that we are not
21 contributing knowingly or unknowingly to the -- if you
22 will, which we don't have a standard definition for --

1 gray market. And we do the same thing if we find that
2 the customers who agree that they are the administers
3 or dispensers, the final administers or dispensers of
4 the products that we purchase from the manufacturers
5 and distribute, when we find that they are not engaged
6 in what they have warranted to be -- and that is final
7 dispensers or administers -- we take appropriate action
8 as well and do not engage in business actions with them
9 as well.
10 So we're doing our part in terms of trying to
11 minimize -- if I use your term correctly -- leakage. I
12 think the states have a role, and I think the states
13 need to be engaged in this process as well.
14 MS. WINCKLER: Our next session is the open
15 public comment period -- I'm sorry. Anita, would you -
16 - Anita, please comment.
17 MS. DUCCA: Just a very quick comment. We
18 have 34 wholesale distributor members that are primary
19 full-service, full-line distributors. And just to go
20 on the record that HDMA has advocated at the various
21 state levels for stricter licensure for wholesale
22 distribution.

1 DR. BERNSTEIN: Susan, can I ask a question
2 to the panel?
3 MS. WINCKLER: Please.
4 MS. BERNSTEIN: Let me just say though,
5 earlier you said you categorize some of the comments
6 into prevention solutions and mitigation solutions. The
7 gray market is a consequence. Fixing that is not going
8 to help prevention or mitigation. It does have to be
9 fixed. We need an effective good track-and-trace
10 system in the United States, but that's a consequence,
11 a result of shortages.
12 But I'd like to ask the panel a question
13 because one of the things we heard a lot this morning
14 is directed FDA, we need to provide better information,
15 put more communication out there in terms of what's the
16 problem, when is it going to be resolved. But we're
17 limited in terms of what we find out from the
18 manufacturer. And we're limited also in terms of what
19 we can say because of certain confidential -- because
20 of laws.
21 So I'm just going to throw out a plea in
22 terms of if people are putting on FDA that we need to

1 be more open and transparent we need to be able to also
2 have the other way around, have companies be more open
3 and transparent in terms of the information, what's
4 happening, why is it happening, and when will it be
5 resolved. So I'm just going to throw that out to the
6 panel.
7 MS. WINCKLER: Comments.
8 MR. MOORE: I think that's a good point.
9 It's absolutely a two-way street. I believe that. And
10 as I'd mentioned in my earlier comments, I definitely
11 think that we've seen tangible results from improved
12 communication certainly over the last 24 months with
13 the agency, the Office of Drug Shortages, and their
14 communications within CDER and so forth.
15 But I actually acknowledge from the industry
16 standpoint we need to be as transparent as possible
17 with the agency, and I can say that it has been
18 broadcast through Hospira from our CEO, our new CEO,
19 and I think some of my fellow GPhA members up here and
20 industry providers are acting in that way going forward
21 as well.
22 DR. BERNSTEIN: And we appreciate greater

1 transparency with us but also the public as well too.
2 MS. WINCKLER: Any final thoughts from the
3 industry panel? Yes.
4 MR. MEACHAM: Maybe I'll start. I just
5 really want the group to know and everybody listening
6 in that we are doing everything in our power to
7 alleviate the drug shortage. We are working our
8 factories 24 hours a day, 7 days a week. It is a
9 number 1 priority at our company. We recently have
10 examined all of the molecules, all of the drugs in our
11 portfolio, and have identified those that are on drug
12 shortage or where APP is essentially the only supplier,
13 and we have moved those to the top of the list.
14 Now that doesn't mean you don't have trade-
15 offs, and so we have to watch that very carefully as
16 well, but it is the number 1 priority of our company,
17 and we spend a lot of time on it every day.
18 MS. WINCKLER: Thank you, Scott. Jon.
19 MR. KAFER: And Dr. Bernstein, to your point
20 around prevention and to some of the comments earlier.
21 I think without question the best prevention is to be
22 able to manufacture product deviation free, and we

1 understand that, and we're putting systems in place so
2 we're much more efficient on that line. And the better
3 we control it coming out of the facility, the less
4 chance we have on creating these types of challenges.
5 So we are doing the exact same things. We're going
6 through complete redundancy and focusing in that area.
7 To that end, I also have seen tremendous
8 collaboration within the drug shortage and
9 manufacturing community. And to your point -- and I
10 made this in my earlier comment -- I don't think it is
11 just FDA's responsibility to communicate the shortage
12 information to the public and to the clinics and to the
13 hospitals that use these products because the
14 manufacturing community is providing that input, but
15 there needs to be a disciplined, coordinated
16 communication plan amongst all stakeholders so we're
17 not reacting to misinformation and we're reacting to
18 the best information available at the time.
19 MS. WINCKLER: Ralph, would you like the
20 microphone?
21 MR. NEAS: The final thing I would like to
22 say, Susan. I mentioned my background at the beginning

1 for a purpose. I believe it's the major reason that
2 the GPhA member organizations asked me to take over the
3 job, the 30 years of coalition building and try to
4 achieve a consensus. And all last week and last night,
5 the six of us, the eight of us, collaborative efforts
6 was what we heard the most not only internally but
7 externally. And what Tom and both said everyone has
8 said from this side of the table to everyone in the
9 audience and everyone up here is we really do want to
10 collaborate in every way possible.
11 And I would hope that this important step
12 will be followed by the next step when we're asked to
13 come in and meet with FDA, meet with Office of
14 Generics, and others, Drug Shortages, Compliance, and
15 try to figure out in concrete ways how we can
16 collaborate and address this issue and other issues.
17 Thanks.
18 MS. WINCKLER: Great. David or Maya?
19 Okay. So I think our takeaway I think from
20 all of these panels and a good segue into the final
21 open comment session it's rare that you face a problem
22 that has one immediately identifiable and implementable

1 solution. And if there's one take-away message from
2 today, I think that's clear that there is not a magic
3 solution that's available.
4 But we know have another hours of time
5 available for open comment. We do have a list of folks
6 that we will go through and then have some time for
7 open discussion.
8 So, Dr. Cox, if you want to announce the
9 first one, and then I'll go to my seat and help us
10 through this last session.
11 DR. COX: Thanks, Susan. Our first speaker
12 this session we'll ask Scott Knoer to come to the
13 podium. And again, we'll allocate three minutes for
14 each speaker. We ask folks to introduce themselves,
15 describe their affiliation, and try and stick to the
16 three-minute timeframe. Thank you.
17 MR. SCOTT KNOER: Thank you very much for the
18 opportunity to speak today. I'm Scott Knoer, the chief
19 pharmacy officer of the Cleveland Clinic, which
20 consists of a 1,300-bed academic medical center anchor
21 and nine community hospitals. I can tell you that
22 we're experiencing absolutely every issue that has been

1 described here today.
2 My first comment is to confirm the high cost
3 that drug shortages have added to an already stretched
4 healthcare system. We at the Cleveland Clinic employ a
5 full-time pharmacist whose entire job is to deal with
6 drug shortages and recalls. And while Chris is a
7 really nice guy, there's nothing I'd rather do than put
8 him out of a job. It's just a terrible waste of
9 resources that we have to spend that to deal with drug
10 shortages.
11 I'd also like to talk about the labor cost of
12 our medical staff, our buyers, and purchasers and our
13 clinical pharmacists, who have to run around and deal
14 with these on a daily basis. The University of
15 Michigan survey presented earlier today stated that
16 $216 million of labor is spent annually dealing with
17 drug shortages, and the Premier data today demonstrated
18 that $415 million in additional cost to their members
19 combing drugs and labor.
20 Next, as we just discussed here, I would
21 advocate for greater transparency in communication
22 regarding drug shortages. It's extremely difficult for

1 caregivers to deal with drug shortages when we don't
2 know the cause of over 50 percent of the cases as
3 presented by our colleagues at the University of Utah,
4 Drug Information Center. How do we plan and
5 communicate with our patients when we're not aware of
6 the full issue?
7 Third, I would like to commend the dedicated
8 staff of the FDA as they struggle along with us with
9 this Herculean task of drug shortages. It's clear from
10 the many comments that we've heard today from our
11 national associations and our peers that have spoken
12 the FDA is very engaged although underresourced.
13 There is one thing that has not been
14 mentioned today that I'd like to put out there that may
15 help some of us. There is a rather unclear process
16 called shared services. This process could potentially
17 allow multi- hospitals health system to centrally
18 repackage products into different dosage forms to use
19 for the hospitals within their system. This can allow
20 us to extend our supply and reduce waste when shortages
21 arise.
22 In summary, if large health systems like the

1 Cleveland Clinic are experiencing these kinds of
2 serious issues with drug shortages, I can only imagine
3 how difficult it is for small and rural hospitals who
4 don't have our resources. In many of these hospitals,
5 the drug shortage pharmacist is also the director of
6 pharmacy, the buyer, and maybe even the chemotherapy
7 compounding technician on occasion.
8 So thank you very much for the opportunity to
9 share our thoughts with you.
10 MS. WINCKLER: Thank you. Our next speaker
11 is Dr. Laura Porter.
12 And the two speakers after Dr. Porter will be
13 Dawn Stefanik and Sara Shull.
14 DR. LAURA PORTER: Hi, I'm Dr. Laura Porter.
15 I'm with the Colon Cancer Alliance. I am a patient
16 advocate and medical consultant for the Colon Cancer
17 Alliance, which is the oldest and largest patient
18 advocate organization dedicated to colorectal cancer.
19 Colorectal cancer is the second leading
20 cancer killer of men and women, and the reason that I
21 bring that up is because of the 22 oncology drugs that
22 on the shortage list five of them are for colorectal

1 cancer. There are nine approved drugs for the treatment
2 of colorectal cancer, and five of them are on the
3 shortage list; 5-FU, fluorouracial, and leucovorine are
4 both the backbones of treatment. You've heard of
5 FOLFOX and FOLFIRI that have been mentioned today. The
6 5-FU and leucovorine are the backbone of that, and
7 there are shortages of both.
8 I want to say also that the generics are the
9 ones that are in short supply. Of the five drugs that
10 are on the list, four of them are the generics. And
11 that brings me to irinotecan, and I want to use
12 irinotecan as an example.
13 Last year there were eight manufacturers of
14 irinotecan. As of right now, there are two, and the
15 FDA has just recently ask another pharmaceutical
16 company -- I believe it's APP -- to start manufacturing
17 the irinotecan. My concern is if single-source
18 producers are required to give a 6-month notice before
19 the stop manufacturing why can't all manufacturers do
20 that? Because what happen is obviously when the number
21 decreases, the demand increases for those who are left
22 to manufacture it.

1 I also want to -- I just want to say that
2 what can we do as patient advocates -- I'm a stage IV
3 colon cancer survivor. I was diagnosed eight years
4 ago. I had two recurrences in my ovary and my liver,
5 my pancreas, and all my abdominal lymph nodes. I am
6 alive today through the grace of God and also because I
7 was able to get the chemotherapy that was recommended
8 for me. And I've been cancer free now for five years.
9 What do we say to our patients that call --
10 we get about 10 calls a month -- that they couldn't get
11 their chemo? And what can we do as an organization, as
12 a patient advocate organization to help facilitate a
13 solution to the problem? And thank you very much for
14 letting me talk.
15 MS. WINCKLER: Thank you. We'll next hear
16 from Dawn Stefanik. And again, following her will be
17 Sara Shull and then Leslie McGorman.
18 MS. DAWN STEFANIK: Hi, my name is Dawn
19 Stefanik, and I'm a nurse manager at the Sandra and
20 Malcolm Berman Cancer Institute at the Greater
21 Baltimore Medical Center, and I'm also here to
22 represent the Oncology Nursing Society today.

1 On behalf of the Oncology Nursing Society, we
2 want to thank you for the opportunity to provide our
3 perspective and recommendations regarding the current
4 shortage of cancer drugs that are facing the nation.
5 ONS, the largest professional oncology group in the
6 United States composed of more than 35,000 nurses and
7 other health professionals exists to promote excellence
8 in oncology nursing and the provision of quality care
9 to those individuals that are affected by cancer.
10 As an oncology nurse, every day I see the
11 physical, the psychosocial, financial, and other
12 challenges that people diagnosed with cancer face. And
13 of course, that was before the additional thing with
14 the drug shortage. People with cancer and their family
15 members have significant concerns. They worry about
16 whether or not there is enough of a particular drug
17 available for the treatment, and if they don't have one
18 available, what other drug will they be getting.
19 ONS believes that people with cancer should
20 have uninterrupted access to specific drug or multi-
21 drug treatment protocols that their healthcare provider
22 determines is most appropriate for this particular

1 cancer. We join with our other colleagues in the
2 cancer community in expressing our deep concern about
3 the adverse impact that current and future oncology
4 drug shortages could have on patient outcome, the
5 viability of ongoing and planned clinical trials, and
6 in addition, healthcare costs.
7 Of serious concern are the reports that the
8 oncology drugs shortages are causing treatment delays;
9 clinical trials to be delayed, suspended, or cancelled;
10 and also rationing of care when physicians have to
11 figure out if they only have a certain amount of a drug
12 who is going to get that drug and how much of it are
13 they going to get; also changes in treatment and/or
14 protocols and some patients having to be switched to
15 other protocols that may be less effective and also may
16 have worse side effects.
17 ONS also understands that under full range
18 and current policy the responsibility for drug
19 shortages or unavailability reporting rests with
20 healthcare providers including oncologist and oncology
21 nurses. We join with our colleagues in the oncology
22 community in urging the drug manufacturers to be

1 required to give the agency advanced warning with plans
2 of stopping to make a particular drug and notice of
3 unplanned manufacturing interruptions.
4 Furthermore, we urge the FDA to work with
5 manufacturers to build in more production line
6 redundancies, particularly for drugs that are
7 vulnerable to shortages.
8 ONS also believes that all entities involved
9 in the drug supply and the purchasing chain should
10 design and implement policies and practices to ensure
11 as products move back and forth through the supply
12 chain that all transactions and products are
13 legitimate, products have been manufactured and stored
14 appropriately, and that all entities participating in
15 the supply chain are verified and licensed.
16 Lastly, ONS urges that Federal policymakers
17 both within the administration and Congress work to
18 identify and enact additional policies and practices
19 that will address the core factors that have been
20 identified as the root cause of the shortages. We know
21 that drug shortages facing the nation threaten
22 patients' health, well-being and outcome and undermines

1 the completion of certain clinical trials to test new
2 therapies, treatments, and protocols.
3 We stand ready to work with the FDA and other
4 stakeholders to ensure that people with cancer have
5 access to timely, comprehensive, quality care
6 (inaudible) (audio problems -- loud noises). Thank
7 you.
8 (Laughter)
9 MS. WINCKLER: Thank you, Dawn, for grace
10 under static. Our next presenter (audio problems --
11 loud noises) we're hoping to resolve this, but I'll
12 invite Sara Shull to come forward, and we'll see how
13 much of your statement we can hear clearly. If it
14 continues too much, we'll suspend for a few minutes
15 while we get the AV issues resolved
16 MS. SARA SHULL: Hi, my name is Sara Shull,
17 and I'm a pharmacist, and I'm the manager of the drug
18 policy program at the University of Wisconsin Hospital
19 and Clinics in Madison, Wisconsin. I concur with many
20 of the statements that have been made this afternoon,
21 and so most of my statement will be related to
22 questions.

1 Several weeks ago, we became aware of an ad
2 hoc distribution allocation of a therapeutic agent by a
3 private manufacturer where we could request drug on a
4 per-cycle basis. At that point, we had none of this
5 particular agent; and still weeks later, we still don't
6 have any of this agent.
7 Our first concern when we opened the
8 application was that it was based on a first-come-
9 first-served basis, the allocation as was presented in
10 this application. We ourselves had heard of the
11 allocation opportunity just before it began.
12 And so my first question is whether a first-
13 come-first-served method is equitable for drug
14 distribution when information flows at a variable rate
15 across the rate and even within a huge provider
16 organization like ours but outside of the established
17 drug distribution channel.
18 Our second concern arouse when we realized
19 that the application required disclosing patient
20 identifiers along with the dose that these patients
21 were receiving and the cycle of progression. We
22 suggested a link-coded identifier but were told that we

1 needed to complete the application as was presented. Of
2 course, we could obtain signature from our patients to
3 waive their HIPAA rights for protected health
4 information, but these patients at that time 15 of them
5 were located across Wisconsin and in northern Illinois.
6 Again, we were working within the first-come-first-
7 served timeline as the basis of the allocation.
8 And so my second question is should patient
9 identification identifiers ever be required to get drug
10 in a shortage situation when these drugs are supplied
11 anonymously when supply is normal? Should a patient
12 have to consider revealing their identity in order to
13 get drug? Or should an institution have to make this
14 decision by signing a business associate agreement.
15 My third question is how is this information,
16 including the clinical information, used by a private
17 company? And how does the identification of the
18 patient affect the amount of drug that is available?
19 I also thank CDER and the FDA today for all
20 of their efforts to avert shortages. It directly
21 impacts how we spend our time and money at the
22 University of Wisconsin. And I very much appreciate

1 it. Thanks.

2 MS. WINCKLER: Thank you. We'll next hear

3 from Leslie McGorman and then following will be Andrew

4 Sperling and Dr. Emil Engels.

5 MS. LESLIE MCGORMAN: Hello, I'm Leslie

6 McGorman here representing the Infectious Diseases

7 Society of America including our over 9,000 members who

8 are infectious disease physicians and scientists. And

9 I'd first like to start off by thanking the FDA for

10 hosting this workshop.

11 Like many stakeholders here today, IDSA

12 members are acutely concerned with drug shortages

13 specifically with anti-infective shortages and their

14 impact patient care and the broader public health.

15 Anti-infective shortages force infectious diseases

16 practitioners to choose alternative treatments regimens

17 that often include drugs with greater toxicity, poorer

18 treatment outcomes, or prolonged and expensive duration

19 of treatment.

20 Unfortunately, antimicrobials are in a class

21 of drugs in which many people have allergies, which

22 puts greater pressure on the few drugs that we have.

1 The problem is even more acute for pediatric
2 practitioners because of tolerance in infants and
3 children.
4 Anti-infective drug shortage is also
5 exacerbating the growing problem of antimicrobial
6 resistance. Limiting a practitioner's ability to
7 provide the anti-infective with the narrowest spectrum
8 appropriate for treating a specific infection resulting
9 in the use of a broad spectrum drug, ultimately
10 pressures the microbial flora of patients in
11 institutions into resistance mutations.
12 Shortages also compromise patient health by
13 forcing practitioners to use unfamiliar or less
14 familiar agents sometimes at an inappropriate dose and
15 duration. This is further complicated by the lack of
16 new antimicrobials in the drug pipeline, equating to
17 even fewer alternatives during times of shortage.
18 As many people have pointed out today,
19 (inaudible) physicians have seen more and more
20 shortages especially in the last couple of years. I'm
21 not going to take the time to list them. But there's
22 also global concern with the limiting number of drugs

1 used to treat malaria and tuberculosis. So that's an
2 additional concern.
3 Unfortunately, we hosted a workshop much like
4 today's workshop in 2000. And out of the workshop,
5 which also included FDA and CDC representatives, there
6 are a number of recommendations. Unfortunately,
7 they're relevant today just like they were then. So we
8 haven't seen a whole lot of progress.
9 But just briefly, we very much support
10 strengthening communications between FDA, the
11 pharmaceutical corporations, healthcare practitioners,
12 everything that's been outlined here today already.
13 Additionally, our practitioners are very much
14 in need of guidelines that'll help them use alternative
15 agents so that they can provide the best patient care
16 possible as well as treating drug shortages within a
17 healthcare facility as an extension of disaster
18 planning in which hospitals and other health systems
19 have a strategy and awareness campaign to manage them.
20 So in summation, we applaud the efforts that
21 the FDA has done so far, and we're here to support you
22 in finding additional solutions and making sure they're

1 implemented. Thank you.

2 MS. WINCKLER: Thank you. We'll hear from

3 Andrew Sperling.

4 MR. ANDREW SPERLING: Good afternoon. I

5 thank everyone for -- it's been a very long day and a

6 very informative day for many of us. My name is Andrew

7 Sperling. I'm the director of legislative advocacy for

8 NAMI, the National Alliance on Mental Illness, which is

9 the nation's largest organization representing people

10 living with serious mental illness and their families,

11 disorders such as schizophrenia, bipolar disorder,

12 major depression, etcetera.

13 I want to talk to the panel today about two

14 particular instances where NAMI has enormous concerns,

15 and both of these are areas where there have been for

16 years less expensive generic alternatives available.

17 The first category I'd like to talk about is the long-

18 acting injectable form of haloperidol, which is on the

19 FDA's shortage list and has been for quite some time.

20 This is an older typical antipsychotic medication, and

21 it is used in only very limited instances.

22 This is a drug that has very severe side

1 effects associated with it including a condition known
2 as tardive dyskinesia, which is a permanent
3 neurological disorder, and there is limited demand for
4 this product, but nonetheless, it is an important
5 demand. It is an invaluable clinical tool in dealing
6 with acute psychosis on a short-term basis and
7 typically in inpatient settings. This is where there
8 are enormous adherence challenges, and it, quite
9 frankly, is an important tool and very difficult to
10 find in many cases. And again, it's been on the FDA's
11 shortage list for quite some time, something that we
12 want to see the agency move forward to try and make
13 this more available.
14 The second one I'd like to mention is the
15 extended release versions of stimulants used to treat
16 ADD and ADHD. As you know, as you heard earlier, these
17 are Schedule II controlled substances. And here the
18 situation is much more difficult and much more complex
19 largely because of the role played by the DEA, and
20 there has been a lot of discussion about this today.
21 And we'd like to drive that point home that
22 the FDA can do a lot to alleviate this by using their

1 existing authority to adjust annual quotas and use that
2 authority to allow manufacturing capacity to rise on a
3 quicker basis, allow quick response where there are
4 acute shortages of these drugs.
5 And we would note for the record we've heard
6 from our members around the country in some cases where
7 the brand is still available and the generic is not.
8 And this, again, shifts enormous cost to the patient
9 and their family as they're forced to pay much, much
10 significantly dramatic higher copays when only the
11 brand is available.
12 So we would urge the FDA to work with the DEA
13 and the Department of Justice to try and get the
14 agency, the DEA, to use their existing authority to
15 allow increases in manufacturing capacity to meet
16 demands. Thank you.
17 MS. WINCKLER: Thank you. Dr. Emil Engels.
18 And then we have Dr. Joel Zivot, Dr. Rick Blum, and
19 Judi Jacobi.
20 DR. EMIL ENGELS: Thank you for providing me
21 an opportunity to share my perspective on the drug
22 shortage with you. My name is Emil Engels, and I am a

1 practicing anesthesiologist at Fairfax Hospital in
2 Northern Virginia. Our practice is located at a large
3 tertiary care hospital, and we provide 80,000
4 anesthetic per year. We provide cardiac anesthesia
5 services, pediatric anesthesia services and pain
6 management services. In addition, we have one of the
7 busiest labor wards in the country with over 11,000
8 deliveries per year. Our practice is part of larger
9 company called American Anesthesiology, which provide
10 anesthesia services in several states and employs over
11 700 anesthesia providers.
12 To be very direct, drug shortages jeopardize
13 patient safety. When faced with a shortage, providers
14 must often ration medications. When the medication
15 supply is exhausted, providers must choose alternative
16 medications that are less effective and have
17 undesirable side effects. At time, the success of a
18 procedure is placed at risk. In addition to making
19 care less safe, drug shortages decrease the efficiency
20 of care delivery and add costs to healthcare system.
21 In order to illustrate how these shortages
22 affect care, I will present several real examples from

1 my own practice.
2 For much of the last year, succinylcholine
3 was in short supply. Succinylcholine is a short-acting
4 muscle relaxant. Anesthesiologists use this medication
5 to facilitate placing a breathing tube in a patient,
6 but it is also used to treat a life-threatening
7 condition called laryngospasm or closure of the vocal
8 cords preventing breathing.
9 Recently, I was caring for a 7-month-old
10 infant who was having an upper endoscopy. During the
11 procedure, the patient had an episode of laryngospasm,
12 subsequently making it difficult to ventilate and
13 maintain consistent oxygen saturations. I quickly
14 administered succinylcholine; laryngospasm broke, and
15 the patient recovered completely with no ill effects.
16 Succinylcholine was truly lifesaving in this instance.
17 If succinylcholine was unavailable, I
18 would've had to administer another muscle relaxant, but
19 none of the other choices work as quickly as
20 succinylcholine. In addition, if one were to use
21 another muscle relaxant, the effects of the muscle
22 relaxant would persists past the conclusion of the

1 procedure, requiring the breathing tube to left in
2 place until the effects of the drug abate.
3 Another medication that was in short supply
4 recently is propofol. Propofol is a medication that's
5 used to induce anesthesia or put patients to sleep, and
6 it's also used to maintain anesthesia. It is short
7 acting and has a very low instance of nausea. It's
8 used in many outpatient procedures like tonsils and
9 hernia surgery.
10 When propofol was in short supply, I was
11 required to use alternative medications to anesthetize
12 patients in the outpatient operating rooms. As a
13 result, patients woke up slurry with the conclusion of
14 surgery. More children awoke with agitation or emerged
15 as delirium than if propofol had been available. In
16 addition, more patients suffered from postoperative
17 nausea and vomiting. This led to decreased
18 satisfaction with the anesthesia care and increase
19 recovery room time and cost.
20 And just one more, a personal story I have
21 for you about my wife who was diagnosed with breast
22 cancer five years ago. Thankfully, she's now breast

1 cancer free, but you can imagine how shocking it was to
2 find out that a healthy 40-year-old mother of three had
3 a potentially deadly disease. Our life was thrown into
4 upheaval.
5 Fortunately, we live in a country with a
6 sophisticated medical system that provides patients
7 with the best and most current treatment options.
8 Cancer is no longer a death sentence, and patients can
9 realistically believe in a cure. One of the key
10 medications that wife received was Taxol. Taxol is now
11 in short supply.
12 I can't imagine having a family member
13 diagnosed with breast cancer in 2011 and being told
14 that a lifesaving medication, Taxol, may not be
15 available.
16 As I hope these example illustrate, drugs
17 shortages affect the delivery of care to patients in
18 this country. At times, patient's safety is
19 jeopardized. The shortages also affect the quality of
20 care, the cost of care, and patient satisfaction.
21 Finally, the efficacy of certain treatments may be
22 diminished because of the use of alternative

1 medications. Thank you very much.
2 MS. WINCKLER: Thank you. Dr. Zivot.
3 Okay. We'll go to Dr. Blum.
4 DR. BLUM: I apologize for putting my name on
5 the list, but nobody answered my question yet, okay. I
6 asked it at least -- well, between me and others -- I
7 was going to ask it again this morning, but someone
8 else beat me to it twice. I asked it several times
9 during the last full-day meeting I attended. This is
10 another full-day meeting I've attended. Nobody's
11 answered it yet.
12 What's happened in the last few years to
13 cause the problem we've had here? Nobody's answered
14 it. The people that can answer it are the people we've
15 heard from this afternoon. There are smart people in
16 this room that know the answer to that question, yet
17 nobody is willing or able to do it publicly. So I'm
18 going to try a different tact. I'm going to give you a
19 straw dog -- a straw man answer, and then you can tell
20 me how full of crap I am.
21 I think it is contraction. I think two
22 things have contracted. I think the number of makers

1 have contracted to a relatively smaller number, and I
2 think the number of purchasers has contracted more, to
3 three or somewhere around there. And the result is --
4 I have to be careful how I state this so I don't libel
5 myself further -- the result is similar to what
6 happened with a large retail entity within the United
7 States that's virtually cornered on the general retail
8 market. They basically say "We're only going to pay X
9 amount of money for your widgets. If you don't like
10 it, tough, because we control 90 percent of the market
11 share in general retail, you know, business.
12 I think that's exactly what's happened here.
13 I think those there purchasers and those few number of
14 makers are playing a gigantic game of chicken with us
15 in the middle. It's actually the patients in the
16 middle, but I consider myself a patient advocate, so
17 I'm going to include myself in that. And they're
18 banking, both of them are banking on someone else
19 coming in from a regulatory or Federal level and giving
20 them the advantage in this game of chicken. And I
21 think that's it in a nutshell.
22 And I may be full of crap, so tell me how --

1 if that's not the answer, tell me what it is because
2 I've asked the question by my count seven times over
3 two meetings, and one has taken it on yet.
4 MS. WINCKLER: Thank you. Dr. Jacobi.
5 MS. JACOBI: I think I have a partial
6 question -- or partial answer to that question. I'm
7 Judi Jacobi. I'm past president of the Society of
8 Critical Care Medicine.
9 And when we're talking about shortages, we're
10 very often talking about shortages of healthcare
11 practitioners as well. The number of critical care
12 professionals that are in training and going to be
13 available in the future is diminishing in relationship
14 to the number of critically ill patients that we are
15 caring for partially due to the aging of the
16 population. I can't state if that's a relationship
17 with drug shortages, but potentially the population of
18 patients that we're treating is a factor.
19 The Society of Critical Care Medicine would
20 like to thank the FDA and the panelists who have been
21 hard at work on this subject for their work and
22 continuing work. In respect to our members, we have

1 over 15,000 physicians, nurses, pharmacists, and many
2 others who are dedicated to the care of critically ill
3 patient.
4 Our patients include the neonates that you've
5 heard a little bit about today as well as the most
6 elderly. They're in our intensive care units not on
7 purpose; usually, it's an unplanned visit. And we have
8 a number of lifesaving interventions that we need to
9 provide with very narrow benefit-to-risk ratios. When
10 we've been faced with drug shortages, we've had to use
11 alternative agents, many of them are not as
12 satisfactory, some cases very difficult to use, and
13 certainly tax our health and safety systems that are I
14 place in order to maximize their benefits.
15 And I applaud the efforts that have been done
16 so far to address these important issues and hopefully
17 the additional efforts that will be ongoing.
18 And if our manufacturing partners are willing
19 to build redundancy and a little bit of excess into the
20 system, we certainly applaud that because it may or may
21 not be the best business decision. But at the point
22 that we somehow address these shortages and are looking

1 to the future, I think another important factor that we
2 need to recognize -- and I suspect those you live on
3 the East Coast probably recognize more than I do from
4 the Midwest is the impact of a major disaster, whether
5 it's environmental or manmade and further disrupting
6 our supply chain and altering a availability of these
7 products for the patients that we already have let
8 along those who are injured in that disaster.
9 So while I hope you can at least build some
10 redundancy, that notion of a stockpile, certainly some
11 sort of emergency stockpile to be able to ramp up in
12 the event of an emergency, should also be on the
13 agenda. Thank you.
14 MS. WINCKLER: Thank you. That completes the
15 list of folks who signed up before the break to offer
16 public comment. We did want to open the microphones
17 one more time if anybody would like to raise a
18 question.
19 MS. SWEET: I'm Gundy Sweet from the
20 University of Michigan. I'd like thank the FDA for the
21 opportunity this morning and again for right now. There
22 was a comment raised in this afternoon's session that I

1 found to be amazingly simple and equally brilliant, and
2 that came from Michael Mone -- I hope I said your name
3 right, Michael -- from Cardinal, and it was the
4 suggestion that we need to begin with standards
5 definitions so that we're all speaking the same
6 language.
7 Having taught in the university setting now
8 for more years than I care to admit, you know you make
9 a brilliant comment when everybody takes notes; and
10 when he made that comment, several people immediately
11 took note, myself included.
12 The need for that became really apparent to
13 me with a question that came later on this afternoon
14 from Bona, when she ask the industry if a product is
15 returned to market, why is it that the end user is not
16 seeing that product. And the response that we got --
17 from I think it was the gentleman from Bedford -- was
18 that it can take two to three months for a product to
19 return back fully to the end user in the supply chain.
20 And I thought about that as somebody who has
21 to develop action plans on a regular basis and realized
22 that when I'm developing action plans I'm developing it

1 based on the date that's provided by the pharmaceutical
2 industry. And if that's really the date at which I can
3 expect to receive product, I'm targeting the wrong
4 date. And it became really apparent to me that a very
5 simple thing like using the same language can really
6 make an impact in our daily practice.
7 Now while I realized that in no way is a
8 solution to the problem, the underlying problem of
9 solving drug shortages, I think it could really help
10 those of us who are dealing at the point of care on a
11 daily basis to be more effective in the solutions that
12 we put out while we're working on solutions to the
13 bigger problems, the root cause of why drug shortages
14 are happening. Thank you.
15 MS. WINCKLER: Thank you. If there are no
16 other comments or questions from the audience, I'll
17 give the panelists here one more time. Does anyone
18 here around the table want to speak?
19 MR. KAFER: I would certainly not want my ER
20 doctor friend from the South to ask this question the
21 eighth time, so I will do my best to try to respond.
22 When you look at what has happened in the industry and

1 when you understand the sterile manufacturing suite,
2 clearly there have been facility-related issues that
3 have impact the ability to make multiple products at
4 one time. So when you have a manufacturing facility
5 that has a disruption, you may take down one or two
6 products. And please keep in mind they're in suites.
7 So you make you cytotoxic, your oncology products in a
8 cytotoxic oncology suite. If you're doing work on that
9 suite, that means you are unable to make any one of
10 those oncology products until that's fully remediated.
11 If you look at the data that's been presented
12 over the spike and increase over the last three years,
13 2010 we took a jump significantly. I don't have the
14 data in front of my head, but was from 24 in 2009 to a
15 significant number. In that period, there were several
16 facilities at various stages of disruption on or about
17 the same time, which does leave little time to respond
18 to the historical volumes of those that have exited the
19 market temporarily.
20 So truly, the driving factor in that spike
21 was limited manufacturing capabilities, certainly not
22 due to consolidation but to facility disruption. That

1 was in my opinion what would've created a lot of that
2 spike.
3 As indicated, we have seen consolidation in
4 the industry. But I think as Tom Moore of Hospira
5 clearly indicated, it's not specific to the injectable
6 space, and we are actually expanding capacity where we
7 can, and we're also building redundancy where we can.
8 Does that help the problem today? No. Will it help
9 alleviate the stress on the supply chain down the road?
10 Absolutely.
11 So this notion that there is no investment
12 being made or that we're not willing to make products
13 for pennies, there's hundreds of millions of dollars
14 being invested in supply chain to assure that capacity
15 and the reliability long term.
16 So I think if you look at I think it was 50
17 to 54 percent of reported shortages in that spike were
18 manufacture related. That is what really created, in
19 my opinion, the initial jump. Now are we on our way to
20 recovery? I do believe we are. Several of those
21 facilities that were down for a period of time are
22 making product again.

1 But also to the point from the University of
2 Michigan on terminology. To say that we're back in
3 production means we're making product. It takes four
4 to five weeks to release that product based on testing
5 required. So I think there is a little bit of
6 nomenclature, if you will, that we should probably
7 discuss, and it does take time to fill the supply
8 chain. So if we go back into production on November 1
9 -- for easy math in my head -- that'll make the first
10 lot produced available for release in early December.
11 That'll make its way in the supply chain a few days
12 later that starts to fill that funnel, and it does take
13 a couple of months. I hope that helps, my friend.
14 DR. BLUM: Why is that a new phenomena? Why
15 is that something that's just reared itself in the last
16 few years? I have to believe that there have always
17 been production problems that occur.
18 MR. KAFER: You have never had a situation
19 where you've had several facilities go down at one time
20 on similar technologies. What I mean by similar
21 technologies, that manufacture similar products. So
22 the physical capacity to produce in a given time was

1 interrupted, and now we're in the process of
2 rebuilding.
3 I can't recall in the 20 years that I've been
4 in this business a situation which you have had
5 multiple similar facilities -- if you have an oral
6 solid dosage form, it's very different. When you're
7 pressing tablets and capsules and putting them into a
8 bottle, there's a lot of different variabilities out
9 there. When you're manufacturing an injectable
10 product, you have to configure your facility to
11 accommodate very specific vial sizes, neck sizes; you
12 have to fill the head space. There's a lot of
13 requirements that are very different than dropping a
14 capsule into a bottle.
15 And so what appeared to have happened in 2010
16 you had several facilities in a similar area that had
17 disruptions, and now we're in the process of rebuilding
18 that.
19 MS. WINCKLER: Thank you. We did have one
20 question for the panel that was submitted anonymously,
21 and this is the last question that we have. I will
22 paraphrase so say it was asking questions about a

1 chemotherapy used in cancer drug trials that is not
2 available, but they were looking at using EU-sourced
3 products. The requirements from FDA to use the
4 European Union sourced products were quite extensive
5 and may have had challenges getting information to
6 support using the alternative product.
7 To further paraphrase it, I think the
8 question to you, Dr. Cox, is what are the opportunities
9 if you're pursuing a clinical trial and have a drug
10 shortage and want to use alternative product from
11 outside the country?
12 DR. COX: So in the setting of an IND where
13 you're using products, one of the critical things is to
14 understand the identity of the product that's being
15 used. And it sounds like from the question there were
16 questions about being able to obtain information on the
17 product that was being proposed for us in the clinical
18 trial.
19 It sounds like there is an ongoing discussion
20 with the division on this particular topic, and I think
21 this is a good topic to talk with the division on to
22 understand what types of information might be needed to

1 try and understand the quality of the product. It's
2 just like any product used under IND it's critical to
3 understand enough about the product to be sufficiently
4 comfortable with the quality of the product for use
5 under IND to make sure that it will perform as
6 expected; it won't have consequences due to either
7 inadequate quality of the drug either with regards to
8 safety or efficacy.
9 So I'm sure there was a complex discussion
10 going on with the division, and I think it's obviously
11 something that's probably worth talking with the
12 division to try and figure out what type of information
13 may be available.
14 And it sounds like too from the question
15 there also particular challenges in that the product
16 that's being used -- obtaining information about the
17 quality of the product given that the party that's
18 proposing to use it is not the party that's actually
19 manufacturing the product. And understandably, that
20 could be a much more challenging the setting of not
21 having the information from the manufacturer about the
22 quality of this product that's not approved for use in

1 the U.S.

2 So complicated issue. I think best the best

3 thing is to talk with the division more and try and

4 work through the issue further.

5 Okay. So at this point, I'll try and just

6 provide sort of a high-level recap of some of the

7 things that we heard over the course of the day,

8 recognizing that -- I think we all took a lot of notes.

9 There's a lot to digest here, so obviously I won't be

10 able to touch on all issues, but I just want to touch

11 on some of the things that were heard over the course

12 of the day.

13 And I think probably most important, at the

14 beginning of the day we started by hearing from

15 patients, and we started to hear from patients about

16 the issues that drug shortages create and the important

17 public health issue that drug shortages are currently

18 posing.

19 Another common theme I think as we went

20 throughout the day from all the stakeholders -- and I

21 want to thank all the speakers, panelists, folks who

22 joined us, folks who joined us on the Webcast for being

1 here today -- throughout all the presentations and
2 discussions we heard the commitment from folks to try
3 and address this important public health problem.
4 We heard about the impact on patients, delays
5 in therapy, using alternative agents that are less than
6 ideal that may have increased adverse effects, and that
7 this affects many different areas of medical practice,
8 oncology, anesthesia, parenteral nutrition,
9 antibacterial drugs, to name a few. And I don't mean
10 to exclude others, but it seems to be an issue that's
11 affecting all areas of medicine.
12 We also heard about the impact in the area of
13 clinical trials. The other things that we heard too
14 was that some of these modifications to regimens that
15 folks may be in a situation where they need to go to
16 alternatives may create issues with medication errors,
17 the differences in practices, the differences in the
18 way folks are approaching patient care.
19 We also heard discussion about guidelines or
20 recommendations as to how to approach alternative
21 therapy in the setting of a drug shortage.
22 Another general topic area beyond that of

1 impact on the patient was that of information. We
2 heard a lot of discussion about information and
3 information sharing; discussions about clarity of
4 definitions and common vocabulary; the idea of
5 increased reporting of information to FDA so that
6 information could be available. And then also comments
7 too from manufacturers that they see an important role
8 in manufacturers also communicating this information.
9 And then some discussion of that in fact the
10 information that we obtain at FDA in the Drug Shortage
11 Program is largely voluntary, and information that we
12 obtain from manufacturers from their voluntary
13 participation with us.
14 There was discussion about the type of
15 information to be communicated and what would be
16 helpful to practitioners such as reasons for drug
17 shortages and being able to estimate durations as best
18 as possible so that folks could make plans; time the
19 resolution of a shortage to the extent that that might
20 be possible. And then also targeting information to
21 particular healthcare group either through listservs or
22 other vehicles to try and get information to those who

1 need it.
2 We also heard discussion about communication
3 with healthcare providers within an institution and
4 that ideally those communications are going on in
5 advance of the healthcare provider learning of a
6 shortage in the setting of a particular patient need.
7 And then the next topic area where there was
8 discussion -- and this was present throughout the day -
9 - was the issue of gray marketers; concerns raised
10 regarding the pedigree of drug products that are
11 obtained through gray marketers.
12 And also I think throughout the day we heard
13 some of the complexities with regards to understanding
14 exactly how the gray market works, and mention of
15 additional general information on this topic could be
16 helpful.
17 We heard throughout the day about the
18 complexity of the issues faced with regards to drug
19 shortages from complex economics issues. We heard
20 about product quality issues as being the major cause
21 of shortages which we're currently experiencing,
22 particularly in the area of sterile injectables.

1 We heard questions about the status of
2 manufacturing infrastructure, and then subsequent
3 information talking about the works that going on to
4 construct new facilities that will be available in the
5 future to try and address some of the issues with drug
6 shortages that we're seeing.
7 We heard people talking about stable supply
8 chain and a stable marketplace for medications and that
9 a stable supply will certainly help to address a number
10 of the issues that we're facing.
11 Discussion about redundancy and some of the
12 challenges in qualifying a new API or manufacturing
13 lines.
14 We also heard too of discussions of industry
15 picking up a product that they previously produced, had
16 stopped producing, and began to produce the product
17 again or picked the product up anew in order to be able
18 to provide a needed product in the setting of a drug
19 shortage.
20 And then also request for additional
21 information to understand best how to report drug
22 shortages. That was information for industry.

1 And then the issue of accelerating recovery,
2 capacity redundancy, and obtaining redundancy or
3 increased capacity is not always an easy thing to do
4 but that there are efforts being made to try and
5 increase capacity; and again, that will take some time.
6 Unanticipated shortages will continue to be
7 difficult issues to address.
8 And then we heard some about dynamic
9 allocations of the available products. There was some
10 discussion about the issue of fair and equitable
11 distribution and the idea of product distribution based
12 on past buying practices.
13 And I'll stop there. And just bring us back
14 to sort of where we started, and that is I want to
15 thank everyone for joining us here today, for all the
16 comments that were provided. I found the session to be
17 very helpful, and I'm sure that many folks share that
18 thought. And really the reason that we're all here and
19 trying to work through this problem is for the care of
20 patients. And I want to thanks everybody for joining
21 us and their commitments to the area.
22 And with that, I'll close. Thank you all

1 very much for joining us today. Have a good evening.
2 (Applause) (Whereupon, FDA Center for
3 Drug Evaluation and
4 Research Drug Shortage Workshop was concluded.)
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