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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACY COMPOUNDING

ADVISORY COMMITTEE

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Friday, July 14, 2000

8:30 a.m.

Advisory Committee Conference Room 1066
Food and Drug Administration
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1 drastically compromised when they are compounded and, as a
2 result, do pose a serious threat to public safety.

3 The first area of concern that I would like to
4 speak to you about is the unit dose inhalation vials. The
5 FDA has long recognized the importance of sterility for
6 these inhalation products. Nonsterile products that are
7 introduced into the lungs pose a safety risk, but, often,
8 these patients are already immunocompromised because they
9 are either elderly or they have a disease.

10 Therefore, the FDA has always imposed the
11 strictest standards of manufacturers to insure sterility.
12 The manufacturing that we do is all done, or performed, in a
13 high-containment filling area. This means that there are
14 hepafilters that continually clean the air. It also means
15 that access by personnel is extremely restricted and those
16 that do enter must wear an air-suit gown before entering.

17 Also, all equipment, tanks and filling equipment
18 are clean-steamed sterilized before each and every batch.
19 High-purity water is used in all preparations and there is
20 a sterile filtration of the product.

21 The resins that we use in the vials are high-
22 temperature heated rendering them sterile and pyrogen free
23 before they are filled. Procedures are in place to insure
24 there are no traces of other drug product that could
25 possibly contaminate the product and as well stability

1 testing is done on every batch that can verify that the
2 product is sterile eighteen months after preparation.

3 These are the standards that we impose and we meet
4 to insure the public safety of inhalation products that we
5 produce are sterile. Sterility has not waned as a public
6 safety issue in the FDA's view and it is still evident
7 because the FDA has recently issued that sterility
8 requirement for aqueous-based drug products that becomes
9 effective in May of 2002.

10 Just to mention the same issues of sterility also
11 apply to morphine for intrathecal use and also for cafcit
12 oral solution which is administered to premature infants who
13 don't even have a developed immune system.

14 A second reason why inhalation products should be
15 considered seriously is because of the containers in which
16 they are packaged. It has been demonstrated by FDA, by us
17 and by others, that the low-density polyethylene vials allow
18 impurities to migrate into the product. As a result, we, as
19 manufacturers, are not even allowed to affix a label to
20 these vials.

21 Rather, we have to emboss the name of the product
22 on the vial and then we have to enclose all these low-
23 density polyethylene vials in a foil pack to prevent
24 exterior contaminants from migrating in. Migration of
25 contaminants is really a safety hazard, so much so that one

1 manufacturer has recently recalled 60 of its own lots
2 because there was a migration of packaging material into the
3 product.

4 I have not even heard this being considered to
5 date. Packaging and compounding would probably have to meet
6 some kind of standards as well.

7 Another area of concern, however, and grave
8 concern, quite frankly, is the use of benzalkonium chloride
9 in many of these UDV vials. It is used as a preservative in
10 many compounded formulations, but the difficulty is that
11 this product has been used to show bronchoconstriction.
12 This is exactly the thing that the medications are trying to
13 prevent.

14 So we do not use this preservative in our
15 component formulations exactly for this reason.
16 Nonetheless, it is routinely used by compounders. Because
17 it is an adjunct ingredient, it is not required that the
18 compounding pharmacist reveal this or disclose this to the
19 patient.

20 So, if the patient has bronchoconstriction, they
21 don't know if it is from the benzalkonium chloride, or they
22 say to their doctor the drug is not working. So that is
23 another area that I hope you will consider.

24 Finally, at this time, anyway, there is no
25 mechanism in place to gather adverse events on compounded

1 products. As manufacturers, of course, we are required to
2 gather this information and report all these adverse events,
3 but when you consider that approximately 50 percent of all
4 inhalation UDVs are being compounded in the State of Florida
5 and there is no way of gathering this information as to the
6 ill effects that the process may have, that is also a grave
7 area of concern.

8 So, for these reasons, for sterility, stability,
9 packaging containers and nondisclosure of potential--of
10 adjunct ingredients and, perhaps, not a safety-reporting
11 mechanism in place, I would hope that you would consider
12 looking at UDVs as one of those products that would be
13 placed on a negative formulary.

14 Do any of you have questions for me?

15 DR. JUHL: Questions from the committee?

16 DR. SELLERS: Can you comment on the quality of
17 bulk materials that are used in manufacturing sterile
18 products?

19 MS. GUZZO: I can, to some limited degree. I can
20 tell you that, for instance, morphine for intrathecal use;
21 we, as manufacturers, start with a sterile, dry-powder
22 product. Our morphine is sterile to begin with.

23 If, in fact, you come in with a nonsterile
24 product, a bulk ingredient product, sterilization of that
25 after the fact is almost impossible. So I don't know, Sara,

1 if that goes to your question. But, other than that, if you
2 would need more information, I am happy to provide it for
3 you at a later date.

4 DR. JUHL: I have a question. The compounded
5 products that you are speaking against, and I guess without
6 naming drugs or products, I am wondering are they
7 essentially copies of commercially available products?

8 MS. GUZZO: Yes; exactly.

9 DR. JUHL: So that they are already in violation
10 of the--

11 MS. GUZZO: Yes; exactly. There is information
12 that I can provide to you. I think we are not here today to
13 talk about the difference between manufacturing and
14 compounding, but when you walk into a nursing home,
15 100 percent of those patients are receiving a compounded
16 product when, in fact, commercial product is available, I
17 think that that is directly the issue.

18 As you know, I am a pharmacist and there is a need
19 for compounded products, but this may be that line that you
20 are speaking of, Randy.

21 DR. JUHL: The venue in which these products are
22 used are primarily nursing-home, institutional, settings,
23 outpatient or is it a variety that--

24 MS. GUZZO: It is a variety. Yes.

25 DR. JUHL: Thank you.

1 Other questions or comments?

2 MS. GUZZO: I appreciate the time. Thank you very
3 much.

4 DR. JUHL: Thank you.

5 Next we have comments from Shelley Capps,
6 International Academy of Compounding Pharmacists. Shelley?

7 MS. CAPPS: Good morning. Thank you. Initially,
8 the International Academy of Compounding Pharmacists was
9 prepared to make a scientific presentation today. Upon
10 reading the issues for this meeting, we asked our previous
11 representative at this meeting, Gina Ford, to attend and
12 speak.

13 Gina is compounding pharmacist who would have
14 addressed the more practical concerns that were talked about
15 yesterday. However, because this committee has already
16 voted and made recommendations on all but one issue, we did
17 not want to waste your time and, instead, will just submit
18 comments to the FDA by the August 15 deadline.

19 Instead, what I would like to do today is to
20 discuss our disappointment in the procedural design of this
21 meeting. I would like to offer some suggestions about how
22 the Academy can and would like to work with this committee
23 in the future.

24 Ideally, the concept paper would have been
25 published well in advance of this meeting. The public would

1 have been given at least 45 days to comment on this paper
2 and then the committee would have been apprised of the
3 public comments prior to the meeting.

4 As it now stands, the committee has made
5 recommendations only a few days after the concept paper was
6 published without the benefit of thoughtful comments from
7 practitioners in the industry that will be directly affected
8 by this concept paper. The public was given less than 15
9 days notice of this meeting. The public was only given two
10 days to respond and request to present at this meeting.

11 The concept paper was released on June 29. This
12 is only two business days prior to requesting participation
13 here today. FDA's extensive bibliography has still not been
14 put on display at FDA dockets. This makes it far more
15 difficult to review the references cited by FDA. All of
16 these factors have severely hampered input to this panel.

17 In addition, no agenda was provided. If it had
18 been given, Gina would have requested to participate in the
19 first day's discussions and would have been available to
20 address practical concerns.

21 The issues you have addressed are critical to our
22 membership, pharmacists who work with tens of thousands of
23 physicians who treat millions of patients. This network of
24 professionals and patients puts us in a unique position to
25 provide this committee with information.

1 For example, yesterday, the committee had
2 questions about 4-AP. If ICP had been notified in advance
3 of this discussion, we would have been prepared to assist
4 the committee. The committee suggested a stability study
5 for this substance. With three months' notice, we could
6 provide this information to the committee.

7 In closing, we believe this committee has been
8 greatly disadvantaged because public comment here has been
9 limited. As I stated yesterday, ICP believes strongly that
10 this concept paper strays from Congressional intent for
11 determining what is to be considered demonstrably difficult.

12 As stated twenty-five times in the legislation,
13 including four times related to demonstrably difficult, a
14 drug product and not a technique or class of delivery
15 systems must be proven demonstrably difficult. For this
16 reason, we believe that the concept paper, itself, is
17 flawed.

18 Had notice been given and public comment allowed
19 prior to this meeting, this legal argument could have been
20 made and resolved. I only address these issues--I know you
21 have pointed out that it is a legal issue, but I only
22 address them because I want to convey to the committee that
23 we very much want to work within this forum and help this to
24 be an effective meeting.

25 Thank you.

1 DR. JUHL: Thank you very much.

2 Let me kind of go through by point. We will have
3 some additional information on 4-AP at the end of the
4 meeting I think will get us past the point we were
5 yesterday. With regard to the design of the concept paper
6 and its treatment by class, I would invite comments by the
7 committee, not on the legal basis but on the common-sense
8 versus non-common-sense approach that was taken on this.

9 I think that would be helpful to the agency
10 although the legal issue that specifically is raised is a
11 different one, my one opinion is this seems to be a common-
12 sense way to approach the issue, again avoiding the question
13 as to whether or not that is within the strict legal reading
14 of the law.

15 Are there other comments on that that the
16 committee would like to offer?

17 MR. TRISSL: I couldn't agree with you more. The
18 issue is demonstrably difficult to make correctly without
19 having these facilities and equipment and training and
20 procedures all in place. It is not a molecule-specific
21 problem. It is an issue that spans the entire spectrum of
22 drugs and, unlike stability, which would be molecule-
23 specific, this is something that applies to anything that is
24 going to be made as a sterile product.

25 So I see no other way to approach this in any kind

1 of reasonable manner but as an issue that spans everything.
2 Unlike, say, the silver nitrate that we put on a list that
3 you can't compound, this doesn't preclude compounding
4 anything. It just says that you must have a certain level
5 of quality assurance to make this in a safe and sane manner.

6 I think it is a perfectly reasonable approach.

7 DR. JUHL: Other comments?

8 DR. PECK: It would appear one has to start
9 somewhere in terms of discussion of drug products that may
10 be compounded. One approach could be to divide the products
11 that might be considered to be compounded into certain
12 groups. It is not necessarily to slot these particular
13 products into this group, but it does happen, the way they
14 are delivered. So the approach here would be to consider
15 the drug delivery system and its complexities.

16 I think what we discussed yesterday, the several
17 that we discussed, I think, thoroughly, can be well defined
18 as products and we can approach it from that standpoint.
19 There are a number of things that were pointed out in terms
20 of what the committee was going to look at and then we had a
21 series of questions that we have to respond to.

22 But I think the original paper did divide the
23 considerations into seven areas of consideration. These
24 have to be looked at in light of the products and they can
25 be put into certain categories, and they can be treated as a

1 group.

2 So we need to, certainly, move on in terms of the
3 deliberations. One way to move on is to group the
4 information under consideration into categories. So I think
5 that is the reason for treating the categories and to try
6 and address the complexities of certain categories of drug
7 products and their delivery.

8 DR. ALLEN: I have just one comment. Many of the
9 presentations yesterday were almost classic academic
10 presentations, you know, that many of us have made. We have
11 made them in the past primarily from an industrial,
12 manufacturing standpoint because those are the factors or
13 considerations in preparing those types of products.

14 But we also have to keep in mind that compounding
15 for an individual patient is different from manufacturing
16 for tens of thousands, or hundreds of thousands, of
17 patients. And I would hope that, of those factors that were
18 discussed yesterday, that we always keep that in mind, that
19 we are not after manufacturing a product for hundreds of
20 thousands of patients but for compounding for individual
21 patients.

22 That would be one of my main concerns. We looked
23 so much yesterday at an industrial orientation as compared
24 to a compounding orientation. Granted, you know, I don't
25 have any problem with what was done yesterday but I would

1 hope in the future that we keep that in mind, that they are
2 two separate things.

3 DR. JUHL: The categories that we considered
4 yesterday were ones that, apparently, no pharmacists are
5 doing yet and all that we had available to us was the
6 industrial model. And all that we had available to us was
7 the industry model, but I would certainly hope if we get to
8 categories where pharmacists are doing them, we would be
9 able to present from both perspectives.

10 DR. SELLERS: Just a follow up. Even if we are
11 compounding for individual patients, we need to have a
12 baseline system established so that each individual patient,
13 their products are compounded in a safe and effective manner
14 and it needs to be standardized.

15 DR. JUHL: Other comments on the approach?

16 MR. RUSHO: Just another comment to follow up on
17 Larry's. If I were to teach the sterilization of each and
18 every individual drug product, first of all, I would never
19 get through the lectures. You have to lump these as a group
20 in order to do it. That is the way we teach our students.
21 It is a rational approach to the problem.

22 DR. JUHL: The curriculum committee thanks you.

23 MR. WELDER: I guess I wasn't aware of the short
24 time span that was afforded this committee on the agenda. I
25 got mine when I got here, I guess. But is there a way that

1 these reports could be issued a couple weeks or so before
2 this meeting so other people can respond and help this
3 committee?

4 DR. JUHL: I am sympathetic to that portion of the
5 Academy's comments.

6 MS. AXELRAD: I would like to address that. First
7 of all, we get it out as quickly as we can. This was
8 actually put up on the web, I believe, at least two weeks
9 before the meeting. It was up on the Internet and available
10 for people to comment on. We put it up on the web at the
11 same time we sent it out to the committee members.

12 Also, I would like to say, this is only the
13 beginning of the public process. We have allowed for a
14 comment period after the meeting where people can submit
15 comments. We will be taking those comments into account as
16 well as the deliberations of the advisory committee at this
17 meeting and preparing a proposed rule on this which will
18 then be published for public comment with an ample period
19 for people to comment.

20 There will be other opportunities for us to bring
21 this and other issues associated with this subject back to
22 the committee. So I think we are at the very beginning of
23 the public process.

24 DR. JUHL: This thing that we have been calling,
25 or at least I have been calling, the White Paper is not even

1 a formal proposal as yet.

2 MS. AXELRAD: That's right. It is not a proposed
3 rule yet. We wanted to bring it to the committee and hear
4 from the committee and then we will develop the proposal
5 which will then, again, be put out for public comment.

6 DR. JUHL: Although that may have been on the web
7 two weeks in advance, the agenda, I don't believe, was.

8 MS. AXELRAD: The concept paper we--

9 DR. ANDERSON: The concept paper, I think, was up
10 June 20-something.

11 MS. AXELRAD: June 20-something. It was up a
12 couple of weeks ago.

13 DR. JUHL: But the agenda wasn't.

14 DR. ANDERSON: The notice for the advisory
15 committee meeting?

16 DR. JUHL: No; the agenda.

17 MS. AXELRAD: The subjects that were covered were
18 in the Federal Register notice. I am not exactly--Igor, do
19 you know when the notice was published?

20 DR. CERNEY: I believe it was about three weeks
21 before the meeting is when the Federal Register notice was
22 published.

23 DR. JUHL: But the issue was that the agenda
24 wasn't published and those that would like to comment on a
25 particular issue that was on a particular day were not made

1 aware of that. The committee--I am assuming we got the
2 agenda as soon as everybody else which was the day when we
3 got here. I think that would be helpful to have that--that
4 may not be regulatorily required, but as a courtesy, I think
5 that if we can do that, it would probably be appreciated.

6 Other comments from the committee?

7 Let me move, then, to Dr. Henri Manasse, Executive
8 Vice President of the American Society of Health-System
9 Pharmacists. He has asked for ten minutes of our time.

10 Henri, welcome.

11 DR. MANASSE: Good morning. Thank you, Chairman
12 Juhl and members of the advisory committee. I am pleased to
13 be here. My name is Dr. Henri R. Manasse and I am the
14 Executive Vice President and Chief Executive Officer of the
15 American Society of Health-System Pharmacists, formerly
16 known as the American Society of Hospital Pharmacists.

17 AHSP is the 30-thousand-member national
18 professional and scientific organization that represents
19 pharmacists who practice in hospitals including outpatient
20 services as well as health maintenance organizations, long-
21 term-care facilities, home-care agencies and other
22 components of organized health-care systems.

23 I am pleased this morning to speak to FDA's
24 Pharmacy Compounding Advisory Committee about our members'
25 perspectives on the concept paper that the agency has

1 developed on drug products that present demonstrable
2 difficulties for compounding because of reasons of safety or
3 effectiveness.

4 ASHP will provide FDA with written comments on the
5 entire concept paper by the 15th of August deadline so I
6 will limit my comments today to the section of the concept
7 paper dealing with sterile products.

8 It clearly would not be in the public interest to
9 ban pharmacist compounding in organized health-care settings
10 of sterile products given the decades long experience,
11 constructive experience, of hospital pharmacists serving
12 patients by performing this function well.

13 Hospital pharmacists in the United States have
14 been providing centralized intravenous admixture compounding
15 services since the early 1960s when the concept was
16 pioneered at the National Institutes of Health Clinical
17 Center and other leading hospitals throughout the United
18 States.

19 In general, we think the FDA has come up with a
20 good approach in dealing with pharmacist compounding of
21 sterile products by recognizing that one, there are risks
22 associated with compounding sterile products and, two, that
23 risk can be managed successfully and effectively if
24 pharmacists follow appropriate practice standards and
25 procedures.

1 I would like to express ASHP's appreciation of the
2 FDA's extensive use in the preparation of its concept paper
3 of ASHP practice standards and guidelines, technical
4 assistance bulletins and other research on this subject that
5 has appeared over the years in the American Journal of
6 Health System Pharmacists, previously known as the American
7 Journal of Hospital Pharmacy.

8 ASHP has demonstrated its serious commitment to
9 keeping all its practice standards and guidelines up to date
10 and reflective of current scientific knowledge and
11 professional practice. I pledge to you that that commitment
12 will continue.

13 Now, on to some concerns. Our first concern has
14 to do with FDA's intentions relating to Section 503A,
15 subpart (f), of the Food, Drug and Cosmetic Act, which
16 states that, "the term 'compounding' does not include
17 mixing, reconstituting or other such acts that are performed
18 in accordance with directions contained in approved labeling
19 provided by the product's manufacturer and other
20 manufacturer directions consistent with that labeling," and
21 I close quote from the law.

22 We believe that FDA's concept paper has not
23 clearly differentiated between the actions noted in Section
24 503A, subpart (f), of the Act, and the commonly accepted
25 professional understanding of compounding of sterile

1 preparations.

2 For example, in discussing the complexity of
3 preparing sterile products, the agency says, on Page 7 of
4 the concept paper, "Each time a pharmacist removes a sterile
5 product from its original container or reconstitutes," and
6 I underscore the word reconstitutes, "a sterile product, a
7 risk of compromising the sterility of the product exists."

8 The use of the word reconstitutes in this context
9 implies to us that the FDA intends to regulate
10 reconstitution according to manufacturers' instructions as
11 well as compounding. We believe that a determination that
12 reconstitution consistent with product labeling as
13 demonstrably difficult would be contrary to the intent of
14 503A, subsection (f) of the Act. ASHP requests that FDA
15 correct this erroneous implication by using a different term
16 or completely deleting any reference to reconstitution.

17 We are pleased that the FDA is advocating that
18 professional practice quality-assurance standards must be
19 applied to sterile product compounding. ASHP agrees with
20 that philosophy as reflected in our long history of
21 developing applicable practice standards and fostering the
22 application of those standards in various articles published
23 in our peer-reviewed professional practice journal and, as
24 well, in our educational program and training conferences
25 and various specific training seminars on this subject.

1 However, if the FDA is suggesting that only the
2 standards in Chapter 1206 of the United States Pharmacopeia,
3 when applied to the compounding of any sterile drug product,
4 would reasonably assure the potency, purity and quality of
5 the drug product, we must object.

6 As you know, just last month, ASHP issued and
7 published its guidelines on quality assurance for pharmacy-
8 prepared sterile products which updates a document
9 originally created in 1993. ASHP believes that the FDA
10 should strongly encourage state boards of pharmacy to base
11 their oversight of sterile drug compounding on both--on
12 both--Chapter 1206 of the United States Pharmacopeia
13 currently in the process of revision and our newly revised
14 guideline for the compounding of all sterile products as
15 well as new scientific knowledge that may not have yet found
16 its way into these documents.

17 ASHP believes it is appropriate for the FDA to
18 suggest to state boards of pharmacy the standards they
19 should apply in the oversight of sterile compounding. This
20 will foster the establishment of a national quality-
21 assurance standard for compounding sterile drug products in
22 all pharmacy-practice settings.

23 The use of both the USP Chapter and ASHP's
24 guidelines as well as the latest scientific knowledge in the
25 literature would provide the assurance the FDA is seeking

1 for the safety and effectiveness of these products.

2 There is little practical difference in content
3 between the ASHP and USP documents. We recognize this.
4 However, in a 1996 article by Laura Thoma comparing Chapter
5 1206 of the USP and ASHP's document, it was noted that ASHP
6 and the USP documents both contain much useful information
7 and each has a unique perspective and contains some
8 information not covered by the other.

9 This was due to the fact that the original USP
10 chapter was limited to home health-care-practice settings
11 while the ASHP document applied to pharmacy services in
12 various and broad practice settings.

13 The ASHP guideline also refers to Chapter 1206 for
14 specific methods such as environmental monitoring, sterile
15 process validation and end-product sterility testing. The
16 ASHP guideline provides useful shelf time and temperature
17 criteria for risk-level determination and the use of
18 barriers and isolators and auto-compounders.

19 The author of the comparison concluded, and I
20 quote, "It is recommended that both documents be read for
21 further information and that professional judgment be used
22 in applying these guidelines to individual practice
23 settings."

24 The role of enforcing the application of specific
25 quality-assurance standards in pharmacy practice is one that

1 is well established in law and in practice for state boards
2 of pharmacy. ASHP believes that the FDA has a role to play
3 in insuring that state boards fulfill this responsibility by
4 encouraging that the standards in both Chapter 1206 and
5 ASP's guidelines are followed.

6 We strongly recommend that the FDA delegate to
7 state boards of pharmacy the responsibility for overseeing
8 pharmacists' adherence to those standards rather than assume
9 this responsibility directly.

10 ASHP has solicited comments from our members
11 throughout the country on the FDA's concept paper which will
12 be incorporated into a written commentary that we will
13 submit to the agency next month. Some of the comments we
14 have already received, however, testify to the many lives
15 that have been saved thanks to the dedication, skill and
16 professional judgment to pharmacists who have compounded
17 sterile products that otherwise may not have been available.

18 The important drug products that provide
19 significant public-health benefits and appropriate patient
20 care should not be considered demonstrably difficult to
21 compound. We look forward to the continued opportunity to
22 advise the agency on this important public-health and
23 pharmacy-practice issue.

24 Thank you for the opportunity to present and I
25 would be pleased to respond to any questions.

1 DR. JUHL: Thank you, Henri. If I could have you
2 just stand by for a second, our next speaker is going to
3 require a computer hookup. I wonder if we could endeavor to
4 do that while we are having some discussion.

5 Let me take the questions that Henri raised and
6 see if we can address them here. The reconstitution effort
7 would appear to be a use of words that we weren't precise
8 in; is that accurate?

9 DR. ANDERSON: No; that's right. We could clarify
10 that. It doesn't apply to reconstitutions within the
11 labeling. It is just compounds.

12 DR. JUHL: So anything that the pharmacist is
13 instructed to do within the approved FDA labeling--

14 DR. ANDERSON: The way the law states; right.

15 DR. JUHL: Is not compounding, legally speaking.

16 DR. ANDERSON: Right.

17 DR. JUHL: The question of guidelines. You have
18 obviously made good use and the ASHP guidelines are
19 certainly respected and useful to pharmacists. Given the
20 Congressional instruction to work with USP and the history
21 of USP as being a legally recognized body for other things,
22 I guess it was quite reasonable and logical that you would
23 choose to use the USP Chapter rather than the ASHP
24 guidelines, even though, as Henri points out, they are very
25 similar.

1 Are there views on the committee about the two-
2 guideline approach that has been suggested as opposed to the
3 singular guideline approach? Loyd?

4 DR. ALLEN: If I could make a request. You know,
5 the new Sterile Products Compounding Committee of USP has
6 just been named. The Chapter 1206 is under constant
7 revision, as you are aware. What I would like to request,
8 if possible, would be any of the components with the ASHP
9 guidelines that are not in 1206.

10 I am sure those are going to be looked at and
11 quite possible or probably incorporated into 1206. I guess
12 what I am asking is if it would be possible to get some type
13 of summary of the information that is in your guidelines
14 that is not in 1206 and that can be presented to the
15 committee that will probably have its first meeting around
16 the 1st of September or so.

17 Is that reasonable?

18 DR. MANASSE: Yes; I think that is quite
19 reasonable. In fact, ASHP does have a standing committee
20 that relates to USP. We can ask for that summarization from
21 our documents and then transfer that to dialogue with the
22 USP. Very reasonable.

23 DR. JUHL: Other comments or recommendations of
24 the agency on the use of guidelines? Elizabeth?

25 DR. McBURNEY: In your paper that you presented,

1 that we got your written comments, you said there is little
2 practical difference in the content between ASHP and the USP
3 documents. Are you aware of any conflicting or discordant
4 information between those two documents?

5 DR. MANASSE: I am not aware of that directly
6 right now, but we will do a careful review and will include
7 that in our written commentary.

8 DR. JUHL: Sara?

9 DR. SELLERS: Are you advocating, then, that these
10 remain guidelines and not requirements?

11 DR. JUHL: The 1206 or the ASHP?

12 DR. SELLERS: Or the combination of both.

13 DR. MANASSE: My impression is that the
14 suggestions of FDA staff is that Chapter 1206 essentially be
15 considered as requirements. ASHP's documents are
16 guidelines, a technical-assistance paper. We don't have the
17 authority of law, if you will.

18 We obviously feel, as I said, that perhaps the
19 translation of ASHP guidelines into state law, particularly
20 that govern the compounding of sterile products, is a
21 reasonable direction.

22 DR. JUHL: Have you reviewed your guidelines in
23 relationship to the NABP proposed section of the Ideal
24 Pharmacy Practice--

25 DR. MANASSE: In the model acts? That is

1 currently in process.

2 DR. JUHL: Other questions on the guidelines? I
3 think the last issue that Henri had raised is the agency
4 delegating to the state boards the authority to overview
5 this. I think that has already happened, although it was
6 probably delegated by the Constitution and not by the FDA,
7 so the agency and the state boards would like to work
8 together on this, but the practice of pharmacy is governed
9 by the states.

10 MS. AXELRAD: I think that the interrelationship
11 between the states and federal government is addressed in
12 the compounding provisions. We will be working with the
13 states, with the states having the principal responsibility
14 in terms of enforcing all of the provisions. But we will be
15 working together, basically, on that.

16 DR. MANASSE: Our underlying recommendation here
17 is to reinforce the fact that all practice acts should have
18 the model language. That is presently not the case and,
19 perhaps, this committee, in its work and its recommendation,
20 could move that along.

21 DR. JUHL: Other comments for Henri? Thank you.

22 DR. MANASSE: Thanks for the opportunity.

23 DR. JUHL: Our last scheduled speaker on the open
24 public hearing is Gregg Jones, Inspector for the State of
25 Florida.

1 MR. JONES: Good morning. I apologize if I seem a
2 little disorganized this morning. I returned from vacation
3 on Wednesday and learned that I was going to be here, so I
4 have put this together pretty hastily.

5 [Slide.]

6 My name is Gregg Jones. I am a pharmaceutical
7 program manager with the State of Florida Department of
8 Health. I work in the regulation of drugs, devices and
9 cosmetics. I have been an inspector for fifteen years this
10 week. In our responsibilities, we monitor the manufacture
11 and distribution of drugs, devices and cosmetics in Florida.

12 The purpose of my visit today is to share with the
13 committee some of our findings in Florida on compounding. I
14 am not here to discuss the safety, efficacy of products or
15 the legal issues but just to give the committee an
16 inspector's perspective of what we see when we go into
17 certain compounding situations.

18 We have seen the compounding of respiratory-
19 therapy medications, in particular, bronchodilator drugs, as
20 the main thrust of all of the compounding that we have had
21 in Florida and I am going to spend the first part of the
22 presentation talking about the large amount of compounding
23 that occurs in that area and some of the problems that we
24 see.

25 [Slide.]

1 I would like to give you a little bit of
2 historical perspective on our dealing with compounding. The
3 best place to start is here with respiratory-therapy
4 medications. In the mid-1980s, Medicare covered nebulizer
5 devices for inhalation of medication. They did not cover
6 the medication that went into the device.

7 A resourceful home-medical-equipment dealer in
8 Florida convinced Medicare that, to be truly effective, they
9 needed to cover the medication. So Medicare began covering
10 albuterol sulfate, among many other respiratory-therapy
11 drugs. Medicare does cover many medications used in the
12 home under Medicare, Part B, despite the common
13 misunderstanding today that Medicare doesn't cover any
14 prescription drugs.

15 The patients, prior to using these unit-dose
16 medications, would be dispensed a concentrated bottle of
17 albuterol sulfate, take this medication home, drop it into
18 the nebulizer using sterile normal saline and administer the
19 medication. The manufacturers, Schering being one of the
20 first, came up with the unit-dose medication that you see on
21 the screen in a 3 cc vial with the most common dose in the
22 0.083 percent.

23 At this point, this became better patient
24 compliance and Medicare's reimbursement rate for this
25 product was somewhere in the range of \$1 per cc--that is \$3

1 per vial, roughly--given three times a day for roughly \$300
2 a month.

3 This was a large amount to pay for these
4 medications but this was based on the brand-name price.
5 What we were seeing in Florida was an escalation in the use
6 of these products because durable medical-equipment dealers
7 were allowed to bill Medicare as opposed to a pharmacy
8 billing Medicare, or a pharmacy billing for drugs which is
9 the traditional way that occurs.

10 Occurring on a parallel track in the mid-80's was
11 a sort of a reintroduction to compounding, in general,
12 basically brought about by a company in Texas that was
13 reintroducing pharmacists to techniques used in compounding
14 and making certain chemicals available to them for that
15 purpose.

16 This is not the compounding that we were seeing
17 escalating at that point. What happened, on a parallel
18 track to that, is that the respiratory-therapy medications,
19 pharmacists in Miami learned that they could take the
20 concentrated solution and place it in the 3 cc vials and
21 continue to bill Medicare, but they started using the
22 concentrated solution.

23 Soon after this, about 1989, they had access to
24 albuterol powders. They started acquiring these from
25 various sources and started to compound what you see on the

1 screen, which is a product made from a powder that has been
2 imported.

3 [Slide.]

4 These are just a few of the many different
5 products that we have seen. There is no consistency in the
6 production of some of these products. They have no lot
7 numbers. Many of them have no expiration dates. They have
8 no indication of the strength and no indication of the
9 quantity.

10 [Slide.]

11 This picture was taken about ten years ago in
12 Orlando in the back of a regular community pharmacy. It is
13 rather difficult to see, but this is behind the traditional
14 pharmacy. This is the storage area for storage of supplies.
15 These are the 3 cc vials. This is the area where the mixing
16 of the albuterol solution is occurring and the filling of
17 the vials and the capping, and this is where the solution is
18 stored after it is mixed.

19 [Slide.]

20 This picture was taken very recently at a pharmacy
21 where they continue to fill the 3 cc vials out in the open.
22 This is in the shipping area of the pharmacy. This
23 particular pharmacy is making a large volume of respiratory
24 medications for pediatric patients using combinations, half
25 strengths of albuterol and other medications as well as

1 antibiotics.

2 [Slide.]

3 This particular pharmacy, about a year and a half
4 ago, was making 30,000 to 40,000 of these unit-dose vials
5 per day, all under compounding regulations. These people
6 sitting at the desk are placing a 30-day supply of these
7 vials into boxes and are labeling.

8 [Slide.]

9 This is the stock shelf where the products are
10 maintained after they have been produced by the pharmacy and
11 then pulled from here for shipping to the patient.

12 [Slide.]

13 Typically, we were seeing, a couple of years ago,
14 that the preservative used for these is benzalkonium
15 chloride.

16 [Slide.]

17 These are just a few of the containers that we
18 have encountered that are used to store the product once it
19 is produced. This is a commercial container, but we often
20 see various types of plastic jugs used to hold the products.

21 [Slide.]

22 Sterile water for irrigation or injection is often
23 what is used to dilute the powder. The powders can come
24 from wide, wide varieties of sources. Some pharmacies
25 import directly through chemical importers. Some buy from

1 some of the major chemical distributors.

2 [Slide.]

3 This picture was taken at a pharmacy in Miami.

4 These are bulk solutions of albuterol sulfate that have been
5 prepared, ready for bottling. As you can see, it is just
6 kept in the refrigerator with the other items such as their
7 lunch.

8 [Slide.]

9 This picture was taken in the bathroom of a
10 pharmacy where stacks of the container-closure systems were
11 kept.

12 [Slide.]

13 This particular photo was taken in Miami where the
14 finished product has been stored in the bathroom. These are
15 the finished vials of albuterol sulfate.

16 [Slide.]

17 Because of the tremendous amount of profit in
18 compounding these products, various home medical-equipment
19 companies developed brochures, they developed sales forces
20 and sales promotional material which would be detailed to
21 doctors. Here you can see an example of what would be given
22 to the representative.

23 A good prescription is written for compounded
24 inhalation solution. A bad prescription would indicate the
25 name of the product. Here, the products, as you can see, it

1 is stated they could be shipped directly. Here, they are
2 not saying they are going to dispense the name-brand product
3 but that they would have to go through the extra step of
4 contacting the physician to change the order.

5 [Slide.]

6 What you are looking at here is the back of a
7 pharmacy. All of these containers have n-acetyl-cysteine in
8 them, one product. I would like to share with you some of
9 the information that has been obtained in the past couple of
10 years on this particular product.

11 Within the past couple of years, the number-one
12 billed product by pharmacies for home respiratory care has
13 become ipratropium bromide. But the acetyl-cysteine, up
14 until about a year ago, was the number-one billed product.
15 In Dade County, the county where Miami is located, there
16 were ten pharmacies that were billing in excess of
17 \$5 million a year for the one product.

18 100 percent of that was compounded. The tenth
19 pharmacy on that list was billing Medicare for more
20 compounded n-acetyl-cysteine than all of the rest of the
21 pharmacies in the country combined. So this gives you some
22 idea of the amount of volume of these products that are
23 being produced.

24 [Slide.]

25 We did some analysis with other agencies on some

1 of the products, and I believe that, out of ten samples that
2 were tested, only one met the potency standards. This
3 particular one, and it is very difficult to read but it
4 failed the assay test with 0.092 percent acetyl-cysteine
5 found which is less than 1 percent of the declared amount of
6 acetyl-cysteine.

7 [Slide.]

8 This, again, is a document to show you how
9 commercialized this has become. This particular company was
10 promoting to pharmacies and to home-medical equipment
11 companies that if you use manufactured respiratory
12 medications, "We can assist you to establish your own
13 compounding pharmacy. We give you the necessary marketing
14 information and you will be able to compound the 3 cc vial,"
15 that I showed you a picture of, "of albuterol 0.083 percent
16 for 12 cents a unit dose."

17 Remember, at that time, the time this was taken,
18 the reimbursement rate was something around \$3 per vial, so
19 you see the huge incentive for making this yourself.

20 [Slide.]

21 I would like to move on to just some of the
22 general findings involving sterile products that we have
23 seen in Florida, quite a few products for use in impotency
24 and injection of prostaglandin products and combination
25 products. I would like to pass around--I have some examples

1 of this and some of these others. I would like to pass them
2 around and let the committee take a look at these, and then
3 I will collect them over here at the end.

4 We have also seen, in some pharmacies, the
5 preparation of preservative-free morphine sulfate. This was
6 for intrathecal administration. Pretty commonly, we see the
7 production of morphine sulfate for use in pumps. It is
8 still occurring, primarily used in hospice situations.

9 We very seldom see any type of testing, potency
10 testing, sterility, pyrogenicity testing, and very rarely
11 any stability testing.

12 [Slide.]

13 This is an example of a pharmacy that is making
14 products for the treatment of impotency. These are the
15 vials where the solutions have been prepared using powders
16 that you see some of them down here. These are the finished
17 syringes that are going to be shipped out to patients.

18 [Slide.]

19 I have some examples of those in here.

20 [Slide.]

21 Pharmacies don't enjoy the privilege of knowing
22 when inspectors are coming and, unfortunately, we walked in
23 right after the Christmas party. But this focus on this
24 area here is where a community pharmacy was preparing some
25 impotency injection using papaverine and prostaglandin in

1 this particular environment.

2 [Slide.]

3 This is where they were storing their empty vials,
4 in the food section.

5 [Slide.]

6 This picture didn't copy very well, but I wanted
7 to demonstrate for you a real typical procedure that we have
8 observed for the production of prostaglandin. This is a
9 vial of spectrum prostaglandin E1 for research purposes.

10 This is a bottle of grain alcohol from the ABC store.

11 Typically, what will be done is some alcohol will be drawn,
12 injected into the vial here to dilute the prostaglandin.

13 An amount of sterile water will be added to the
14 graduate cylinder here, mixed with the powder solution,
15 drawn into a syringe and then transferred through a
16 0.2 micron filter to another syringe and then injected back
17 into an evacuated vial.

18 [Slide.]

19 This is another pharmacy where we encountered the
20 same alcohol, type alcohol, being used.

21 [Slide.]

22 The first picture I showed you, this is a hood,
23 here. Next to it in this compounding room is a bulk
24 container. It think this is a 50 kilogram barrel of
25 sulfadiazine used to compound some veterinary products.

1 [Slide.]

2 This is the area of that room on that very
3 opposite end where a number of various products are being
4 compounded. You can see the condition of that compounding
5 area.

6 [Slide.]

7 This procedure indicates the production of
8 preservative-free morphine sulfate, which Medicare, by the
9 way, does cover and pays a lot more for this particular
10 product than they do the non-preservative-free. This is a
11 small boat that is used to weigh out the morphine sulfate.
12 It is diluted with preservative-free water and then mixed
13 and transferred through 2.2 micron filters to the syringe
14 which is used in the intrathecal pump.

15 [Slide.]

16 Not all of the places that we visit are quite as
17 unclean as the other picture that I have showed you, and we
18 don't often take pictures of the good things we see in
19 compounding. But I don't want to imply from these pictures
20 that everywhere we go, we see nothing but problems in
21 compounding because we do see some very advanced systems.

22 This particular room you are looking at is a clean
23 room in a regular community pharmacy that is doing some IV
24 compounding. They are JCAHO inspected using JCAHO standards
25 for this clean room. They have hepafilter-positive airflow

1 coming into this room. They have another laminar-flow hood
2 where the work is done.

3 They do take some swabs and do some culturing of
4 this area on a periodic basis, so I don't mean to imply that
5 everywhere we go, we encounter a problem because there are
6 some pharmacists that are going to extremes to insure a
7 quality product.

8 [Slide.]

9 This is the pump that I was mentioning to you
10 before which is used in the morphine injection.

11 [Slide.]

12 In this particular pharmacy, they were making
13 pellets for implantation under the skin. These are the
14 machines that are used to press the pellet.

15 [Slide.]

16 This is an autoclave which is used to sterilize
17 the product.

18 [Slide.]

19 This is the finished product here, a pellet which
20 is inserted under the skin for hormone-replacement therapy.
21 That is my thumbnail, so you get an idea of the size of
22 these. This tape is a temperature-sensitive tape which
23 changes colors when the autoclave reaches a certain
24 temperature, which is when the product is removed.

25 [Slide.]

1 This is the dispensing of that product, Estradiol,
2 25--I can't tell if that is milligram or microgram--pellet
3 which is sent to the doctor and then inserted by the
4 physician.

5 [Slide.]

6 As far as the active pharmaceutical ingredients,
7 we have seen all types of products being used, some
8 imported, this one imported from the Czech Republic, this
9 one from an unlicensed distributor in I believe it is
10 Minnesota, and this one, another unlicensed company. This
11 is actually for a research chemical, prostaglandin, from
12 Spectrum Chemical.

13 [Slide.]

14 This product, phentolamine, which is one of the
15 ingredients used in impotency treatments. The common
16 product, prostaglandin used, but it is also being used in
17 combination with papaverine and phentolamine for bimixes and
18 trimixes. The phentolamine, which is the brand name,
19 Regitine, as used primarily in emergency-room situations, is
20 not readily available and it is inaccessible to pharmacists.
21 They have had to obtain this product from various sources
22 and compound it. They virtually cannot get their hands on
23 the Regitine.

24 We went into a pharmacy in a Central Florida town
25 and told them that they are using this phentolamine which is

1 labeled for research purposes only, they had no certificates
2 of analysis on it.

3 The next week, we went to another pharmacy in that
4 general vicinity, and you see what was on the bottom of that
5 same type of label. They have removed this information.

6 [Slide.]

7 I want to briefly touch--I know my time is up--but
8 on a couple of issues that you will be addressing in the
9 future which is sustained-release products. These are bags
10 full of methylphenidate and a diluent. They are filling
11 these bags with hydroxymethylcellulose, I believe. These
12 are methylphenidate tablets. These will be ground up and
13 put into capsules as sustained-release capsules in various
14 strengths, depending on what the doctor needs.

15 Some of these vary from 1.5 milligrams to 35
16 milligrams per cap. This particular unique dose was
17 13.75 milligrams.

18 [Slide.]

19 This is the common sustained-release chemical that
20 is used.

21 [Slide.]

22 These are morphine sulfate which is used in this
23 extensively in hospice situations which are commercially
24 available strengths that are being made.

25 [Slide.]

1 This particular group of controlled substances was
2 taken--this picture was taken in a pharmacy where over
3 80 percent of all their medications they were dispensing to
4 hospices were compounded.

5 I think that concludes it. I am sorry, Mr.
6 Chairman, for running over my time.

7 DR. JUHL: Thank you for the information. Let me
8 ask the obvious question. Do you have the regulatory and
9 legislative power that you need to shut places like this
10 down?

11 MR. JONES: The office that I work in regulates
12 manufacture and distribution of these products. Our board
13 of pharmacy regulates the practice of the profession of
14 pharmacy which includes compounding. Every state differs in
15 how they regulate it but, traditionally, all of the
16 compounding activities have fallen under the purview of the
17 boards of pharmacy.

18 When we find products that I showed you that were
19 grossly under their potency, we have taken action on those.
20 When we see chemicals that may indicate that they are not
21 for human use, we take action on some of those. But, in
22 general, there have been very few actions taken on the
23 actual controls used in compounding products.

24 DR. JUHL: But many of the products that you
25 showed us were essentially copies of commercially available

1 products, the products for inhalation and so on.

2 MR. JONES: I would say the majority of those
3 products have been just copies of the commercially available
4 product. Under Florida law, and I don't know how the other
5 states handle this, but if a doctor orders a product that is
6 essentially similar to a commercially available product and
7 the patient is aware of it, then the pharmacy may compound
8 it.

9 What we have seen, in the Miami situation, is that
10 they will order, in the case of the acetyl-cysteine--it is
11 available, I believe, in 4 ml and 10 ml quantities,
12 commercially, in unit dose, they will order 5 cc's. By
13 ordering the 5 cc volume, the pharmacy then will compound
14 and dispense that amount as opposed to combining
15 commercially available quantities.

16 That is very, very typical. Efforts have been
17 under way by various offices in Miami to educate the
18 physicians because the physician typically will write
19 whatever the patient tells them that they have been taking
20 before and not know what volumes are available commercially.

21 They will write 5 cc's not knowing it is not
22 available. Many of the actions taken on the acetyl-cysteine
23 in interviews with the doctors indicated they were not aware
24 that the product was actually compounded from a powder.

25 DR. JUHL: Federal law now prohibits producing,

1 essentially, copies of commercially available products and
2 they speak to the issue of changing just a little tinch to
3 make it different. Has that been, at the practical level, a
4 useful piece of legislation for enforcement or is it people
5 don't know about it, or--what I am asking is is there
6 anything we can do to be helpful here?

7 MR. JONES: I don't think it has slowed down any
8 of the practices that we have seen involving the respiratory
9 drugs; no.

10 DR. JUHL: Other questions? Rose-Ellen?

11 MS. HOPE: Could you give me some indication as to
12 how frequently a pharmacy in the State of Florida would
13 expect to be inspected?

14 MR. JONES: I believe pharmacies are required to
15 be inspected annually in Florida.

16 MS. HOPE: Okay, because some states, now, it is
17 only about every three years. I am thinking in terms of how
18 long it would take to uncover something like this that was a
19 developing problem in some states.

20 MR. JONES: In Florida, they are inspected
21 annually.

22 DR. JUHL: There appear to be enough inhalation
23 products billed to serve the entire country. Can I assume
24 that many of the products that are being produced and billed
25 are not actually going to patients but just being billed on

1 a fraudulent basis?

2 MR. JONES: I think there is a tremendous amount
3 of fraud involved there. I am not sure they are not going
4 to the patients. They may be going to the patients and not
5 being used, I think is what some of the findings are.

6 DR. McBURNEY: Mr. Jones, thank you very much for
7 coming from Florida on such short notice. We appreciate
8 your presentation. One of my concerns with the data that
9 you presented--could you give us a little perspective as to
10 what numbers we are talking about here in regard to
11 compounding pharmacies. We have seen some overwhelming
12 examples of abuse and inappropriateness.

13 Is this the norm, or is this a small percentage of
14 the compounding pharmacies, to kind of put it in perspective
15 for us?

16 MR. JONES: Most of the photos that I have showed
17 you were taken in an effort to go out and look at some of
18 the areas such as injectables and some of the respiratory
19 situations that we knew posed some public health hazards.
20 But what I can address, as far as volume, is the respiratory
21 element. I talked with a person yesterday who works in this
22 routinely and I think we can safely say that there are
23 hundreds of pharmacies in Miami, alone, Dade County, that
24 are compounding respiratory meds daily.

25 DR. McBURNEY: Of those hundreds that are

1 compounding, could you make a reasonable or an educated
2 guess as to the number that are doing it properly versus
3 improperly?

4 MR. JONES: Most of the smaller pharmacies that
5 are doing that are not following any type of controls in
6 producing them.

7 DR. McBURNEY: The other question; I was not clear
8 from the presentation--you stated that Medicare paid the
9 durable-goods companies for these medications.

10 MR. JONES: Yes.

11 DR. McBURNEY: Are these pharmacies subsidiaries
12 of the durable-goods companies or are they free-standing
13 pharmacies?

14 MR. JONES: Medicare changed their policy in, I
15 believe, it was 1996. Now they will only allow a pharmacy
16 to bill for those medications, so they no longer will allow
17 the home-health company to bill for them. That policy has
18 increased the number of small pharmacies that are now
19 billing and producing those products.

20 DR. McBURNEY: If I understood you correctly, the
21 issue of sterility, that would fall under the board of
22 pharmacy to enforce, not under your agency.

23 MR. JONES: Right; compounding is included in the
24 definition of the practice of the profession of pharmacy.

25 DR. McBURNEY: I see. Thank you.

1 DR. JUHL: Realizing that you are only one state,
2 but could you give us an idea of the interest of the state
3 board of pharmacy to deal with this kind of issue or are
4 they understaffed, underresourced and it is not high on the
5 priority list?

6 MR. JONES: I don't feel really qualified to speak
7 for the board since we work in an entirely separate section.

8 DR. JUHL: How responsive is the board when you
9 provide them with reports of these kinds of activities?

10 MR. JONES: The actions that we have taken, we
11 have taken independently under the Drug, Device and Cosmetic
12 Act under misbranding provisions. I am not sure what the
13 board's actions have been on other violations.

14 DR. JUHL: When you find things that are, in your
15 mind, things that pharmacists shouldn't be doing that the
16 board should have called to their attention, is the board
17 responsive to these kinds of things?

18 MR. JONES: I believe so; yes.

19 DR. JUHL: Thank you.

20 DR. SELLERS: I can state, just from reading the
21 disciplinary actions from the state boards that you rarely
22 ever--I have never seen a disciplinary action taken.

23 DR. JUHL: Bill?

24 MR. RUSHO: Just a couple of questions. On your
25 slide where you showed the prostaglandin being prepared, you

1 said that they injected alcohol into the vial. Are you
2 saying that these pharmacies do not have analytical balances
3 necessary to weigh out that material?

4 MR. JONES: That is a good question. Some do
5 weigh it out with some sophisticated balances. This
6 particular example that I showed you, the company has the
7 stated amount of micrograms on the vial that comes from
8 Spectrum. What they will do is produce the concentrated
9 solution in the--the impotency drugs have disappeared. This
10 would have a concentrated amount of the solution, and then
11 this would be drawn off.

12 I have seen a sample of this sent to an analytical
13 laboratory to actually determine the exact concentration
14 because when you are talking about 10 micrograms as a dose,
15 and you may have 100,000 micrograms in this concentrated
16 solution, they need to make sure that, as they dilute it,
17 they get--you can't just assume that when you start to
18 dilute this 100,000 micrograms, you are going to end up with
19 anything close to your target, 10 micrograms or 15.

20 So they will do--in one case only, I have seen
21 this concentrated solution analyzed as a starting point on
22 how to determine the exact concentration.

23 MR. RUSHO: What I was trying to get at was we
24 talked about some of the difficulties in compounding here at
25 this meeting. One of the things that we were interested in

1 was the proper equipment in order to do to compounding.

2 That is why I was asking you about the analytical balance.

3 MR. JONES: Many of the ones that were making this
4 would start with a given amount of prostaglandin and dilute
5 that and base their further dilutions on the assumption that
6 that was the exact amount that was weighed in the vial and
7 not do any weighing of the product.

8 MR. RUSHO: Have you seen these products being
9 dispensed as generic equivalents?

10 MR. JONES: In Florida, the product is written for
11 albuterol, for instance. That is the common way it is
12 written. The pharmacist can substitute a generic. We don't
13 regulate and we don't see these prescriptions so I can't
14 really accurately say we have seen it. But, the majority of
15 the cases we have worked, when something is written
16 albuterol sulfate, 0.083 percent, dispense a month's supply,
17 they will dispense the compounded whether the doctor has
18 indicated to dispense compounded product or not.

19 MR. RUSHO: So they are using it as a generic
20 equivalent, then, without bioequivalency and bioavailability
21 testing and everything the generic houses have to go
22 through.

23 MR. JONES: Yes.

24 MR. RUSHO: What about the calculations of the
25 drug dosage. I noticed one of the cartons said

1 0.083 albuterol sulfate expressed as albuterol. Have you
2 noticed any problems with the pharmacist calculating that,
3 in accounting for the salt form of the drug and waters of
4 hydration of such?

5 MR. JONES: No; we didn't look at anything as
6 detailed as that.

7 MR. RUSHO: Okay. Thank you.

8 DR. JUHL: Joan?

9 MR. LaFOLLETTE: Could you comment on the scope of
10 the manufacturing? Are you actually seeing manufacturing
11 going on whereas as an industry we are approved for certain
12 batch sizes, or are you seeing things being compounded per
13 patient and per prescription?

14 MR. JONES: Well, in some of the surveys that we
15 did, we did see a lot of compounding done, one prescription,
16 one product would be made. But most of the pharmacies will
17 compound a certain supply based on what they think they are
18 going to dispense. When you look at a bottle of 100
19 sustained-release capsules, they may go through those in a
20 week. So they will make 100.

21 But, to extrapolate that, if you are dispensing
22 50,000 units a week, they make 50,000. So I am not sure
23 what your question is, whether we have seen manufacturing.
24 It depends on the size of the pharmacy. Some of them are
25 rather large and do compound large amounts of those

1 medications.

2 MR. LaFOLLETTE: I am getting at that the industry
3 has to abide by GMP regulations, and a lot of regulations.
4 If you start to see the scope of what I would call
5 manufacturing, from my view, especially of the inhalations
6 on a large scale, it doesn't appear that all of these
7 pharmacies--some may, but it doesn't appear that they would
8 abiding by all the regulations that we have to to insure
9 that the public is receiving a safe and efficacious product.

10 Along with the testing and the data that we have
11 to do, I don't see it demonstrated that they--compounding
12 pharmacy on the scale that some of the abuse that you are
13 showing where it is not demonstrated to me. It makes me
14 very nervous.

15 DR. JUHL: Other comments? Larry?

16 MR. TRISSL: Perhaps you would have no knowledge
17 of this, but I will ask anyway. The examples you have all
18 shown are presumably retail pharmacies. Does this practice
19 of compounding basically copies of the commercial drugs
20 extend to hospitals in Florida as well? Have you seen
21 examples of that on any kind of scale that is approaching
22 this?

23 MR. JONES: No; we haven't.

24 MR. TRISSL: Have you looked?

25 MR. JONES: We haven't looked.

1 MR. TRISSL: I am just checking. Thank you.

2 DR. JUHL: Jane?

3 MS. AXELRAD: I would just like to ask one
4 question. All of the pharmacies that you have shown, are
5 they still operating or have they been shut down?

6 MR. JONES: Many of those pictures you saw, the
7 pharmacies are no longer operating.

8 MS. AXELRAD: That would have been the action that
9 you would have taken or--

10 MR. JONES: Among actions by other agencies
11 including Medicare.

12 DR. ALLEN: With the recent, I guess, enforceable
13 regulations of the USP and the activities of the committee
14 here, is there anything that you are aware of that we are
15 not addressing that would help take care of this problem
16 that you have seen?

17 MR. JONES: I think you are headed in the right
18 direction in addressing these various areas. Without going
19 into pharmacies more often and actually seeing what the
20 current practices are, I couldn't really say that there is
21 anything additional that you need to be doing because I
22 understand, just from listening this morning, that there are
23 various legal arguments that are going to persist in the
24 direction that you are heading now.

25 I think the primary problems that we have had have

1 been in respiratory therapy and then the sterility of the
2 products that are injections. Those are some of the areas
3 that we have seen some of the major concerns.

4 Anything would be better, I think, than what we
5 have now.

6 DR. JUHL: Elizabeth?

7 DR. McBURNEY: Mr. Jones, could I not infer from
8 your comments that the reason that you are seeing it mostly
9 in respiratory is because Medicare is covering the cost of
10 those medications?

11 MR. JONES: I think so; yes.

12 DR. JUHL: Other comments from the committee? If
13 not, I appreciate your coming here. It is not information
14 that I, as a pharmacist, like to see but it does, I think,
15 speak to the issues that we here as a committee have to deal
16 with. One of the definitions of a profession is that it is
17 self-policing. Pharmacy has not done a good job of
18 establishing standards for compounding, translating those
19 standards into regulations and enforcing them.

20 That does a disservice to the many pharmacists who
21 do compounding on a patient-specific basis and do good
22 deeds. This, certainly, is a black eye for us and we
23 appreciate finding out how the real world works.

24 Thank you.

25 MS. GUZZO: I'm Susan Guzzo. If I may, I would

1 like to offer this up to the committee. You raised the
2 point--this is a television commercial that aired where
3 pharmacy compounders are soliciting patients who are on
4 inhalers to convert to unit-dose vials because they can have
5 their medication reimbursed through Part B. It is a public
6 commercial that aired on television, and I will leave it
7 with whomever you think should have it for viewing.

8 DR. JUHL: Thank you.

9 I am going to continue the open public hearing and
10 my next step, now, is to ask if there others who would wish
11 to address the committee.

12 MS. CAPPS: I find this very disturbing and I
13 would like to request a copy of the powerpoint presentation
14 so that we could show it to our pharmacists because I think
15 many of our members would be very disturbed by it as well.
16 That is the best way to make it known out there and, like
17 you say, to begin the self-policing aspect of this and even
18 invite Mr. Jones to come to one of our meetings and make
19 this presentation would be very valuable.

20 So I would like to offer that.

21 DR. JUHL: Thank you. Are there others who would
22 like to briefly address the committee? Larry?

23 DR. SASICH: Larry Sasich, pharmacist, Public
24 Citizens Health Research Group. I do really appreciate Mr.
25 Jones coming. I have seen this presentation before and each

1 time that I see it, I become more outraged than the time
2 before and absolutely at the loss for words.

3 I think one of the issues that this committee has
4 to think about, and it shouldn't have to think about, is
5 there is no longer any affective regulatory route for
6 preventing or protecting the public from these kinds of
7 activities. That was eliminated with FDAMA.

8 If you stop and think, as I have done for the last
9 thirty years, as to one situation, one public-health
10 problem, or one egregious act or series of acts that has
11 been controlled by the self-regulation either of an industry
12 or a profession doesn't work, it simply doesn't work.

13 As I said yesterday, this committee has very few
14 tools and the agency has very few tools to operate within to
15 be able to protect the public health, until, I hope, that
16 FDAMA goes back to Capitol Hill and that it is either
17 totally repealed or there is a serious rewrite of what is in
18 this piece of really, really, bad legislation.

19 One of the things that I think you can do in terms
20 of sterile products that would make it very easy and plain
21 for state board of pharmacy inspectors some of whom are
22 probably not even pharmacists to be able to police this
23 particular situation is to place sterile products or
24 products that should be sterile that are prepared from
25 nonsterile bulk drug substances absolutely on the list of

1 drugs that are demonstrably difficult to compound.

2 What we saw today from Mr. Jones' presentation and
3 the egregious quackery that Jana Nestlerode was subjected to
4 yesterday from injectable DMPS would be prevented. I think
5 what I would like to see you discuss is that possibility of
6 placing those types of compounds on the demonstrably
7 difficult to prepare list unless they are done in an
8 organized health-care facility; i.e., a pharmacy that meets
9 some type of professional standards.

10 I know you are going to have to work out whether
11 these should be requirements or guidelines and, perhaps,
12 differences or similarities between the USP and the ASHP
13 approaches.

14 But that is the only thing that I can see in the
15 short term to protect a large number of citizens from what
16 you surely have to admit is a very clear public-health
17 problem. 50 percent of the oral-inhalation solutions in the
18 State of Florida? That is stealing. The representative
19 from Boehringer Ingleheim was very diplomatic but it is
20 nothing more than stealing.

21 Thank you very much for your time.

22 DR. JUHL: Thank you. Are there other comments?
23 If you are brief, please.

24 MS. GUZZO: Susan Guzzo from Boehringer Ingleheim.
25 Before joining Boehringer Ingleheim, I was a Florida

1 attorney as well and I was called in on several occasions to
2 serve as defense counsel for many of these pharmacists. I
3 can tell you that, in fact, it is manufacturing. I declined
4 the opportunity, after reviewing the cases, at least four of
5 those cases that the HHS was bringing that I was not going
6 to defend the pharmacist there because they were simply
7 manufacturing.

8 Thank you very much.

9 DR. JUHL: We have the videotape cued up. It is
10 only 30 seconds long so we will go ahead and run that for
11 the committee's information.

12 [Video played for the benefit of the committee.]

13 DR. JUHL: Is that a legal direct-to-consumer ad
14 for--

15 MS. AXELRAD: I don't know if it is a legal
16 direct-to-consumer ad, but I believe it is a generic
17 approved product. Day Laboratories has a generic product I
18 think that has been approved.

19 DR. JUHL: But it is not the manufacturer who is--

20 MS. AXELRAD: I don't think it is a compounder.

21 DR. JUHL: Other comments? Larry?

22 MR. TRISSL: I know it is a difficulty sometimes
23 to differentiate between larger-scale compounding and
24 manufacturing, but at the extremes, we can identify easily
25 what is compounding and what is large-scale manufacturing.

1 This would seem to fall into one extreme of those. Does the
2 agency have no regulatory authority over an unapproved
3 manufacturer in this regard?

4 MS. AXELRAD: I think that the whole purpose of
5 the FDAMA provision was to put some structure around our
6 attempts, over the last many, many years to try and
7 distinguish between compounding and manufacturing. The
8 specifics that were put forth in the exemption that it has
9 to be by a licensed pharmacist or physician upon a
10 prescription for an individual patient and then to define
11 the limited circumstances in which you could compound in
12 anticipation of receiving that and the fact that there has
13 to be this close relationship, and then the other provisions
14 that deal with copying regularly or inordinate amounts what
15 are essentially copies of commercially available products,
16 all of those parameters in the law were trying to help us, I
17 think, try and distinguish between compounding and
18 manufacturing.

19 We are going to be addressing a lot of that in our
20 general regulations, but I think it is always going to be
21 very difficult to try and draw the line. Some of these
22 pharmacies that we just saw were making things in large
23 amounts. There will be issues. Are they essentially copies
24 of commercially available products if it is 1 or 2 cc
25 difference in terms of amount.

1 Are they doing it regularly and in inordinate
2 amounts? Do they have prescriptions for individual
3 patients? Is there a real need for a compounded product?
4 Is there a medically significant difference?

5 So all of those things are things that we would
6 have to look at. Also, as we have been talking about, the
7 state boards of pharmacy will have principle responsibility
8 to do something here. I think that it is fair to say that
9 not all states are as aggressive. Some states are less.
10 Maybe they have too few resources or are not able to inspect
11 as often. Maybe they don't have the expertise.

12 But they may not be as aggressive in terms of
13 enforcing this as other states. In those cases, we will
14 have to see where we would be stepping in to do something.

15 MR. TRISSL: I think it is unfortunate that Carmen
16 was not able to make this meeting because the input of the
17 Boards of Pharmacy would be very welcomed in this. Maybe we
18 should solicit that apart from this meeting.

19 DR. JUHL: Loyd?

20 DR. ALLEN: In fact, if I could recommend that,
21 possibly at the next meeting, maybe Carmen could even
22 provide a report on what activities, educational, et cetera,
23 that they are doing for the individual state boards for the
24 enforcement of all of the new things that are going on.

25 MS. AXELRAD: We can certainly try and arrange

1 that. We would love to hear from other states, too, about
2 what they are seeing and what they are doing. We have tried
3 to conduct a survey of a few states to try and find out what
4 they are seeing with regard to compounding.

5 We didn't get a very significant response. We
6 didn't hear from very many states and we also didn't get a
7 lot of information about their practices. I think Florida,
8 we have had more about what is being observed in Florida
9 with regard to compounding pharmacies than any other state.

10 DR. JUHL: Seeing no further comments, we will
11 close the open public hearing portion of our meeting and
12 return to the business at hand.

13 Committee Discussion

14 DR. JUHL: We have before us our last question to
15 consider on sterile products. Let me ask, is there further
16 discussion before we call the question?

17 MR. RUSHO: I think, from my perspective, that the
18 document is not something that I could adhere to at this
19 particular point in time. I think I run a good shop but I
20 think there are provisions in there, as I expressed
21 yesterday, that need to be modified.

22 To use the colloquialism, I think they need to
23 start thinking outside the box. They have taken
24 manufacturing documents and tried to apply those to a
25 compounding pharmacy. That doesn't work. As we heard

1 yesterday, when they do media fills, they are working with
2 one medication at a time.

3 When I am dispensing and working in our IV center,
4 I probably have got twelve antibiotics, pressor drugs,
5 ionotropes, TPN, chemotherapy, epidural drugs and sometimes
6 some sterile compounding in there. It is not feasible to
7 put industry standards onto the compounding pharmacist. I
8 think that document needs to be modified before we can
9 accept it.

10 If we are voting on the concept of some regulatory
11 matters, I think that is a different matter. But if we are
12 voting on adapting that as it is written today, I can't do
13 that.

14 DR. JUHL: I think yesterday we heard that both
15 the USP and the FDA were willing to go back to 1206 were it
16 to be required and revise it in a way that would accommodate
17 the suggestions that were made yesterday to the extent that
18 they can, plus others that I am sure will come forward.

19 So I think the question before us, and we will
20 modify that when we call it, is to use Chapter 1206 as a
21 starting point and not as a final document. Larry?

22 MR. TRISSL: I wouldn't interpret either Chapter
23 1206 or the ASHP guidelines as requiring manufacturing level
24 requirements by any stretch of the imagination. They may
25 have extracted valuable portions of the GMP style of

1 assuring quality but they are clearly aimed at compounding a
2 sterile product in a pharmacy, not a manufacturing setting.

3 Both of those documents being so similar obviously
4 have been developed with a rational, reasonable approach to
5 sterile product compounding in a pharmacy. That is not to
6 say there isn't room, because we have discussed some areas
7 where there is room for improvement, but the general
8 concepts that are embodied there are very applicable to a
9 sterile-product compounding pharmacy.

10 While we should always work toward improving
11 those, I think it is a good starting point.

12 MR. RUSHO: That brings up another point, too. I
13 think these should be standards. I don't think they should
14 be goals because I think people could sit there and say,
15 "Well, I will meet those in 2050." I think these should be
16 the standards. If people are going to compound these
17 different levels of products, they need to meet those
18 standards.

19 DR. JUHL: I think our goal is to translate these
20 into regulations, have them translated into regulations, at
21 the state level that a state board-of-pharmacy inspector can
22 utilize to say this is lawful and this isn't, we need to
23 insure that we start at the top with the Chapter 1206, if we
24 choose that, written in such a way that that can happen.

25 As we talked yesterday, there are guidelines that

1 are written that are stretched standards and there are
2 guidelines that are standards of practice and there are
3 minimal requirements. So there are a number of ways that
4 guidelines can be written and the revisions that would need
5 to occur with Chapter 1206 would have to be done with the
6 state board of pharmacy in mind so that they could be
7 utilized in that way.

8 I think we have made that clear and the agency
9 understands that recommendation from us.

10 Joan?

11 MR. LaFOLLETTE: I would like make the point that,
12 yesterday, when the USP presented, Chapter 1206 could be
13 moved to become a requirement. I actually would be for that
14 and see harmonization between the USP and ASHP's guidance.
15 Right now, even if we revise it with the comments that we
16 made yesterday, it is still a guidance and there are things
17 in there that are lacking.

18 I think it needs to be thoroughly reviewed and
19 made a requirement. Otherwise, we will never move off this
20 mark. We will always be shooting for a future target and we
21 will still probably hear and see problems like we saw today
22 that are occurring in Florida.

23 I think we have to move and be aggressive about
24 this.

25 DR. JUHL: Loyd?

1 DR. ALLEN: With the new Parenteral Compounding
2 Committee with the USP--they will meeting, quite possible,
3 the 1st of September for the first time to establish the
4 goals for this next five-year cycle, one of the things I
5 will carry on to the chair of that committee--I have been
6 making notes on the discussions--would be to look very
7 carefully at harmonization of the current 1206 with the ASHP
8 guidelines, with the NABP model guidelines with JCAHO
9 accreditation guidelines and see what type of document,
10 since this is constantly under revision, to try to get one
11 harmonized chapter which--it has been kind of my goal for
12 the last couple of years to try to get 1206 renumbered down
13 to less than 1000 so that it is required because I think it
14 is very feasible.

15 DR. JUHL: Sara?

16 DR. SELLERS: One specific comment. Reading over
17 the USP guidelines and the ASHP, I didn't see enough
18 attention paid to the quality of bulk actives that are used
19 in sterile compounding. I think that we run a tremendous
20 risk now that these bulk substances are handled through
21 brokers, are available over the Internet. I have seen many
22 ads targeting "compounding pharmacists" over the Internet;
23 "We like to sell to compounding pharmacists."

24 I did not read enough specific regulation with
25 respect to how these bulk substances are being acquired and

1 how we, as pharmacists, can verify that they do meet very
2 specific standards before they are placed into a sterile
3 product.

4 DR. JUHL: Other comments from the committee?
5 Garnet?

6 DR. PECK: Along with the bulk active, and I don't
7 want to interject something that may not be that important
8 to some, but I think the excipients, in general, should be
9 included also along with the bulk active. I don't think we
10 should neglect those. We don't know how much and where they
11 are coming from they are sourcing.

12 The other thing I respect the document by ASHP
13 because it represents something 30,000 members. My only
14 concern is that there be some regularity in terms of
15 revision. The USP works on a five-year cycle and, at least
16 during the five years, something is going on. I would
17 recommend that if these are looked at in conjunction with
18 the USP chapter that ASHP recognize that we need cyclic
19 revision of their document, whether it becomes a guideline
20 or really part of a joint regulation.

21 It has to be revised on a regular basis.

22 DR. JUHL: What would be nice is if we had the
23 same exact document and anybody who wanted to title it and
24 sign on to it and publish it in their journal could well do
25 that. But I think that is one of the advantages of using

1 the USP, that it has a regular, everybody knows about it,
2 cycle for revision and it does have legal standing.

3 Joan?

4 MR. LaFOLLETTE: I just would like to say I agree
5 with the comments that Garnet is making about excipients.
6 There are a lot of areas that we didn't touch upon and, in
7 industry, we have to abide by. I am hoping if we revise
8 some of these things to make them regulations; ICH
9 guidelines for residual solvents? We have certain maximum
10 daily dosing, units and classification of solvents. This is
11 such a broad topic, but there are so many other things that
12 we should be looking at the safety and quality.

13 That goes to Sara's comments about the source of
14 bulk drug substances and the excipients. So, hopefully, if
15 we revise these chapters and harmonize them, and come up
16 with a standard that is regulated, that we take into account
17 some of these other points.

18 DR. JUHL: I think that, in some regard, has
19 already been covered in that excipients, by the law, as I
20 recall, need to be USP, I think, ultimately. Is that wrong?

21 DR. SELLERS: No.

22 DR. ALLEN: The terminology of the ingredients
23 used for compounding that a USPNF chemical is the required
24 component to use if available. If it is not available, then
25 you use the next highest chemical grade that is available to

1 you as a pharmacist.

2 DR. JUHL: Okay.

3 DR. SELLERS: Any bulk chemical that is labeled
4 USP I believe may give a false sense of security.

5 DR. JUHL: Well, if they don't earn the USP label,
6 then that is another issue that needs to be addressed.

7 MR. LaFOLLETTE: And that is true. There is a lot
8 of bulk chemical sourcing and vendors change their process
9 and new solvents are introduced and you can still pass the
10 USP test or other compendias. So it is something that needs
11 to be considered and there are guidelines, as I said, by ICH
12 which encompasses FDA's input in Japan and Europe for
13 residual solvents.

14 DR. JUHL: Additional comments by the committee on
15 the sterile products question in front of us? If I could
16 ask the International Academy of Compounding Pharmacists, as
17 I have on the other topics, are there issues of science that
18 you would like to address to the committee for their
19 consideration of this category of drugs?

20 MS. CAPPS: Shelley Capps, International Academy
21 of Compounding Pharmacists. We will address our science
22 concerns in the submission that we provide to the FDA by
23 August 15. Most of our concerns here are legal concerns.
24 Thank you.

25 DR. JUHL: Okay. Thank you.

1 Any last words from the committee? Let me try and
2 formulate a question that we can respond to. I am reading
3 from our prepared questions. "Do you agree that the class
4 of sterile drug products that are not compounded in
5 accordance with USP Chapter 1206 should be included on the
6 list of products that may not be compounded because they are
7 difficult to compound properly?"

8 Let me add the proviso that we would incorporate
9 all of our comments for revisions and modifications of 1206
10 to meet the standards as we have described them when we are
11 talking about Chapter 1206. So let's put a quote around
12 "USP Chapter 1206" in our discussions. Is that suitable for
13 the committee?

14 Ready for the question? "Do you agree that
15 sterile products that are not compounded in accordance with
16 'Chapter 1206' should be placed on the difficult to compound
17 list?" All those that agree, would you please signify by
18 raising your hand.

19 [Show of hands.]

20 DR. JUHL: Any opposed?

21 [No response.]

22 DR. JUHL: I don't see that. That is unanimous on
23 the part of the committee.

24 Continuing along. "Is 'Chapter 1206' an
25 appropriate standard? If not, what other standard would you

1 suggest we use?" The issue of using dual standards has been
2 suggested. Let's make it clear how the committee feels to
3 the agency for their consideration.

4 Let me phrase it in the singular, as it is, that
5 we would recommend that "Chapter 1206" be utilized as the
6 sole standard but with the hope that we would engage all
7 other standard writers and proposers to participate in the
8 revisions of 1206 so that it could serve as a singular
9 unambiguous standard for the profession.

10 Is that a suitable question and understandable to
11 the committee? All those that agree with using 1206 as the
12 singular standard, please signify by raising your hand.

13 [Show of hands.]

14 DR. JUHL: I see that an unanimous as well.

15 Are there other comments on standards that need to
16 be included for the record?

17 Last question, then. "Should compliance with 'USP
18 Chapter 1206' be required for the compounding of relatively
19 low-risk sterile products from sterile components?" I think
20 we need to go back and review the relatively low-risk
21 products that we are talking about and frame the question so
22 that we have a good understanding.

23 And I don't think I do at this point, so would
24 somebody like to take a crack at that? Larry?

25 MR. TRISSL: Correct me if I am wrong, but I think

1 the agency is asking about products that are simple aseptic
2 transfers from one sterile commercial product into another
3 sterile commercial product where the risk of contamination,
4 although present, is very low.

5 You are asking whether 1206's low-risk category is
6 an adequate standard for those low-risk products; am I
7 correct?

8 DR. ANDERSON: Correct.

9 MR. TRISSL: Certainly, I think that 1206's low-
10 risk category and ASHP's, which is very similar, adequately
11 address that issue. They define a level of facility,
12 equipment and training that is common, or should be common,
13 for all sterile product admixtures, low-risk, certainly, and
14 form a basis to build on for higher-risk products.

15 DR. JUHL: Other comments on this question? Loyd?

16 DR. ALLEN: It does not address pharmacists'
17 preparation but non-pharmacists' preparation of sterile
18 products, physicians, nurses, whether they are in a health-
19 care facility or whatever, if they do admixtures that the
20 patients--or in a facility nearby, in a physician's office,
21 how would this impact them?

22 MS. AXELRAD: The only thing that this will cover
23 is compounding as defined in the statute which includes
24 compounding by licensed pharmacists and physicians, as we
25 indicated yesterday, we will address, in our regulations,

1 and people who compound under the direct supervision of
2 those people, be they nurses or technicians or whatever.

3 So anybody who is engaged in legitimate pharmacy
4 compounding as defined in the statute in our regulations
5 would be subject to this.

6 DR. ALLEN: So, basically, then, they would be
7 required to meet 1206. Okay.

8 DR. JUHL: Would these low-risk kinds of
9 procedures include drying up of a mixture in insulin into a
10 syringe from two vials, for example?

11 MR. TRISSL: It would seem to me that if it is
12 within the parameters of the official labeling of those
13 products, it does not get included.

14 DR. JUHL: Right.

15 MR. TRISSL: That is a nurse drawing it up in the
16 doctor's office for administration or on a nursing unit for
17 immediate administration. But prefilling a hundred
18 syringes and storing them in a clinic for use over the
19 period of the next week or two, that would fall under the
20 parameters of this and that would not be considered non-
21 compounding. It would become a compounding act.

22 DR. JUHL: I guess the specific question I have
23 occasionally a physician preparing an injectable will add
24 xylocaine or lidocaine along with whatever the product is
25 that they are injecting and do that at the time of

1 preparation.

2 Does that fall under this low-risk category?

3 DR. McBURNEY: I can think of two examples. For
4 instance, when we inject cheloids, which are excess growths
5 of scar tissue, it is not unusual to dilute, sometimes, take
6 kenalog 40, dilute that down to 20. Then some people may
7 add xylocaine to that preparation for the injection to
8 decrease the pain.

9 Another example would be in treating acne cysts to
10 take kenalog 10 and dilute it down to 3.3 milligrams per cc
11 with sterile water or saline to inject into the cyst.

12 DR. JUHL: Those are probably outside the official
13 labeling.

14 DR. McBURNEY: I don't think either of those would
15 be within official labeling.

16 MR. RUSHO: I think you are also leaving out the
17 emergency department and some of the other areas of the
18 hospital. JCAHO actually has a regulation governing that on
19 products prepared outside the pharmacy. I would rather
20 defer to that when we get into that area because what you
21 are describing here is more what ASHP describes as a
22 level 2. Isn't that right, Larry?

23 MR. TRISSL: I'm sorry; do you mean like physician
24 offices or something?

25 MR. RUSHO: Well, no. What he was saying, as far

1 as making a hundred syringes, or something like that.

2 MR. TRISSL: Yeah; that would be considered--

3 MR. RUSHO: Or something in storage, like that.

4 But when you are making it and using it immediately, there
5 are a lot of instances I can think of, ICUs, emergency
6 department, all of those, you make those up. They can be
7 reconstituted antibiotics.

8 MR. TRISSL: It is the storage issue that gives
9 time for organisms to grow that becomes a problem.
10 Immediate use is not perceived as a problem.

11 MR. RUSHO: But, if you do that, aren't you
12 getting away from what the USP calls low risk?

13 MR. TRISSL: I do not recall whether that chapter-
14 -Loyd, do you know--addresses length of time. See, the ASP
15 document addresses length of storage because that is a risk
16 factor as well as temperature and all the storage
17 conditions.

18 I think the USP Chapter needs to address that, if
19 it does not.

20 DR. JUHL: I guess my concern is the thing that
21 Elizabeth has described; is that compounding, does it fall
22 in the below-risk, and are we making law breakers out of
23 people who do that is the question that I am asking. At
24 least that is my interpretation of the question we are being
25 asked.

1 DR. ALLEN: Randy, one thing we might look at--
2 incidently, the USP does address multi-day infusions, but we
3 have got to look at the multi-day storage a little bit more.
4 One of the things we might look at in considering, with
5 1206, would be that there would be a dispensing function as
6 a part of it rather than immediate bedside use or patient-
7 side use.

8 DR. JUHL: Jane?

9 MS. AXELRAD: If it is permissible, I think I
10 would like to take the question off the table. I think that
11 we are getting into details here of, you know, what parts of
12 the chapter and how it is going to apply in specific
13 situations that I think can be worked out when we are
14 working with the USP to develop the chapter.

15 You are getting into things that are very much
16 sort of on the fringes. I think that the advice that you
17 have given us with regard to using the chapter as a baseline
18 to start from is good enough.

19 I was going to ask if you wanted to take up the
20 question that Dr. Sasich raised instead of this, which is
21 whether compounding of sterile products from non-sterile
22 products should be placed on the difficult to compound list
23 absolutely without regard to Chapter 1206, sort of the
24 opposite.

25 I thought that it was suggested that the

1 compounding of sterile products from nonsterile components
2 be placed on the list absolutely without any specific
3 standards.

4 DR. JUHL: if we put it on the list without
5 specific standards, then we are saying that it is
6 prohibited.

7 MS. AXELRAD: Right.

8 DR. JUHL: I think Larry addressed that yesterday
9 that, although it is very unusual, there are situations
10 where pharmacists are faced with the situation of needing to
11 use nonsterile products to prepare a sterile product. Do I
12 recall correctly?

13 MS. AXELRAD: I was just suggesting it might be
14 useful to have an official word from the committee on that.

15 DR. JUHL: Are there other thoughts on that
16 question?

17 DR. ALLEN: I think, in 1206, with the high-risk
18 category, there can be additional emphasis put on some kind
19 of end-product testing or procedures that need to be
20 inherent prior to compounding the products from nonsterile
21 ingredients.

22 MS. RIFFEE: Randy, if we are not going to
23 consider, then, how the low risk is handled, should that, in
24 fact, appear in the concept paper because there is a full
25 paragraph on Page 7 that talks about low risk in kind of

1 loose definition.

2 MS. AXELRAD: I think what I would like to do is
3 leave open the question of how the low-risk products will be
4 handled and discuss it in the context of looking at the
5 chapter and the section on low-risk products and how it
6 would apply. Somehow, everyone will be involved in that.
7 We will be working with the USP on that. If there are
8 issues that need to come back to the committee, we can do
9 that.

10 DR. JUHL: I think, at least my concern is, we
11 make sure that practices that don't need to be done in a
12 hood--we are not sending every physician down to the hood to
13 make up an injection if the group that, indeed, is a
14 reasonable practice that can be done safely with proper
15 technique outside the hood.

16 We want to make sure the line is drawn right. I
17 think, as you say, that is something that the details can be
18 worked out. So we don't have to answer that question.

19 I would like to do two more things before we
20 adjourn. One, your suggestions of potential other topics
21 that should be considered for the difficult to compound
22 list. We have had a couple of suggestions throughout the
23 two days that we could make and you could add to.
24 Sustained-released oral products has come up on a couple of
25 occasions as to whether or not it is possible for a

1 compounding pharmacist to prepare a sustained-release
2 product that actually is sustained-release and is safe in
3 that regard.

4 The implantable pellets was raised but I think
5 that is a sterile product and that would fall under that.

6 CAPT SCOTT: I believe they are sterile.

7 DR. JUHL: Well, they are supposed to be; yes.
8 Are there other categories or specific drug entities,
9 compounds, that we should consider? Joan?

10 MR. LaFOLLETTE: I would like to add biotech
11 products to that. We may not be seeing compounding now but
12 it may be something in the future that would come up.

13 DR. JUHL: Could you give me an example?

14 MR. LaFOLLETTE: I am just thinking of the type of
15 products, which I am not going to talk about specifics, that
16 we work with that are very sophisticated. The testing is
17 totally different than the kind of testing that we are
18 talking here. It is not even handled by CDER. It is
19 handled by CBER. Usually, that is the way it goes.

20 DR. JUHL: You are talking about drugs that are
21 composed of proteins?

22 MR. LaFOLLETTE: Yes; and the storage conditions
23 are probably beyond the scope of most pharmacies, maybe not
24 some hospital settings or universities, but unusual
25 conditions and very sophisticated formulations.

1 MR. TRISSL: This products are here now. We are
2 compounding them now in our institution for viral vectors,
3 gene therapy. And we have done them in hospital pharmacy
4 settings because that is the only place to do it.

5 MR. LaFOLLETTE: That is my comment. I didn't
6 know if they were, but it is something that I would like to
7 discuss at a future meeting, possibly.

8 MR. TRISSL: If it is still in business after all
9 the problems they had.

10 MS. AXELRAD: We would only be addressing here
11 products that would be regulated under Section 505. To the
12 extent that a biotech product is regulated under I think it
13 is Section 351 of the Public Health Service Act, it is not
14 addressed by the compounding exemption and we wouldn't be
15 addressing those here. But there may be some biotech
16 products that are regulated as drugs under Section 505 that
17 we could consider.

18 DR. JUHL: Do these include who is in charge of
19 the--you take cells out of a person, treat them and then
20 reinfuse those back into a person. Is that a biologic or is
21 it a drug?

22 MS. AXELRAD: I don't know the parameters of
23 exactly where that line is drawn.

24 DR. JUHL: That is one type of biotech where the
25 viral vectors that are being used are all experimental now.

1 But, at some point, hopefully, something like that will be--

2 MR. LaFOLLETTE: I think what Jane is getting at
3 is we have had certain products developed and they have to
4 be approved, and sometimes they go through CDER and
5 sometimes they go through CBER. So there could be a
6 differentiation, and that is why it could fall into this
7 area of this committee's responsibility.

8 DR. JUHL: Dr. Sasich?

9 DR. SASICH: Larry Sasich, Public Citizen. I
10 would urge the committee to consider looking at antibiotics
11 for children that, in their labeling, are required to be
12 reconstituted by a pharmacist at the time of dispensing, and
13 the reflavoring of those products. This practice is
14 widespread. I have seen nothing to make me feel comfortable
15 that these particular products are stable for their intended
16 use time.

17 Thank you very much.

18 DR. JUHL: There is another suggestion. Garnet?

19 DR. PECK: Although some people may consider it
20 under controlled release, I think enteric coated products
21 should be a separate category.

22 DR. JUHL: Bill?

23 MR. RUSHO: There is also some sustained-release
24 suspensions that are being prepared.

25 DR. JUHL: Any specific drugs as drug compounds,

1 chemicals? Okay. That is a list that the agency can
2 consider reviewing and taking a look at.

3 The last thing I would like to do is clean up on
4 our 4-aminopyridine discussion from yesterday. Jane has had
5 some discussions within the agency and has, I think,
6 something to propose that we do to move us on.

7 MS. AXELRAD: Yes. We have decided that we are
8 going to explore additional ways of making 4-AP available
9 under compassionate use INDs. The paperwork is not very
10 complicated. The chemistry and making sure that the
11 formulation that is being provided to the patient is safe
12 would be the principle issue.

13 What we would like to do is invite ISTEP to work
14 with us on this. We need information about the bulk
15 suppliers. We need information about the formulations that
16 are being compounded. We want to know how many pharmacists
17 are going to be compounding this, how many physicians would
18 be enrolled sort of as investigators--that is sort of the
19 word for it--if there were an IND held, perhaps, by a
20 pharmacist.

21 And we would like to, perhaps, develop some kind
22 of a model submission that could be used by pharmacists who
23 want to compound this and make it available, that we could
24 make sure that the formulation is safe for the patients who
25 are getting it.

1 So what we would like to propose is that we would
2 work with ISTP, if they are willing to do it, and develop
3 something like this. We will not take action, a final
4 action, with regard to 4-aminopyridine until we have had a
5 chance to explore this further and will update the committee
6 on progress as we do that.

7 DR. JUHL: Good. I appreciate your flexibility.
8 Is the Academy willing to enter into at least an
9 exploratory--

10 MS. CAPPS: Absolutely. We would be definitely
11 willing to work with you on that.

12 DR. JUHL: Great. Thank you. Comments by the
13 committee? Does that seem like a reasonable way to proceed
14 on that? Are there other issues that need to be brought
15 before the committee before we bid adieu? Tony?

16 MR. WELDER: Just a comment, since this may be my
17 last meeting with you all. I have enjoyed the meetings. It
18 takes me away from work, and I go to a lot meetings. One of
19 the benefits that I have always said that occurs, for me, is
20 to meet a bunch of great quality people, and this meeting is
21 no exception.

22 I realize the charge of this committee is making
23 recommendations to the FDA and, of course, safety for the
24 patients is number one. I hope that, in future meetings,
25 that you all are aware that another charge that we have is

1 making available those special products that a good
2 compounding pharmacy provides.

3 So I say this is probably my last meeting, and I
4 think an appropriate comment now would be that we all wish
5 our chairman a happy birthday today.

6 DR. JUHL: I would just as soon avoid it if I
7 could, but thank you very much. I will also suspend my
8 usual modus operandi and not offer time for opposing
9 comments.

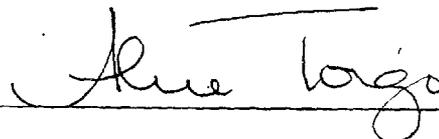
10 Other comments? I would like to thank the FDA
11 staff for their diligence in preparing this meeting for us.
12 I know it is a great deal of work and, after we leave you,
13 you end up with more work. But we do appreciate the
14 efforts. I would also like to thank the members of
15 committee for their thoughtfulness and participation in our
16 meetings. And we are adjourned.

17 [Whereupon, at 10:30 a.m., the meeting was
18 adjourned.]

19

C E R T I F I C A T E

I, **ALICE TOIGO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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ALICE TOIGO

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