

1 was preparing the product. So, I went to a commercial one
2 where I had a series of vials, and they moved the culture
3 medium back and forth, and once again, no growth at all.

4 At this point, I got a little suspicious, so in
5 one vial, I took a needle, and I moved it on my hand,
6 similar to the way you used to sharpen an old straight-edge
7 razor, put it in there, no growth.

8 I finally got an 18-gauge needle and stuck the
9 palm of my hand until I got skin the needle, put it in, I
10 finally got growth. Over at the hospital, we use the same
11 commercial product for our annual employee evaluation and
12 for new employee hire. Once again, no growth.

13 We went to a commercial product that simulated TPN
14 preparation. Once again, no growth. One of the pharmacists
15 took his gloves off once again, put it on his bare palm, put
16 it in, no growth. He finally had to spit in his hand, draw
17 it up in a syringe, and put it into the bag.

18 MR. TRISSEL: At least he didn't stick himself.

19 MR. RUSHO: I think that these are giving people a
20 false sense of security. I would suggest, like I said
21 before, that we replace that with LAL testing, because I
22 think LAL testing is a far superior test, and it will give
23 you the results within an hour. You don't have to wait
24 seven days or 14 days.

25 The employee can get almost immediate feedback,

1 and they can see if they have got good technique or bad
2 technique.

3 DR. JUHL: I would like to congratulate you and
4 your staff on your apparently excellent hand-washing
5 technique. I am not suggesting that jab in the hand go in
6 the USP. A point well taken, though.

7 MR. TRISSEL: Could I ask the agency, obviously,
8 that procedure from the USP was based on or extracted from
9 the use of media fills in industrial manufacturing, at least
10 that was probably the concept of where it came from. As I
11 recall, there are media-filled failures all the time in drug
12 companies. Sometimes whole plants are shut down because of
13 it. Why the difference?

14 DR. COONEY: That is, in fact, true. I can tell
15 you that the media that is used in the media fill programs
16 and commercial manufacturers has to undergo growth promotion
17 testing, where you have to show the support of growth of 10
18 to 100 microorganisms, a whole panel of them, so the
19 growth-promoting properties of that have to be determined.

20 Let me give you an idea in case anyone here is not
21 aware. In a commercial manufacturing operation, companies
22 run media fills, and there is a lot of dispute and a lot of
23 argument internationally about how many units to fill and
24 what is an acceptable criteria, et cetera, et cetera, but in
25 general, companies have no problem at all in filling at

1 least 3,000 vials of media and seeing no contamination in
2 those 3,000 vials.

3 That is where you get the concept that the
4 sterility assurance level for aseptically produced products
5 is about 1 in 1,000 or 10^{-3} . That is where that came from,
6 but it is not really sterility assurance. It is just the
7 rate of failure of your media fill.

8 You talked about the barrier isolators. There is
9 a lot of manufacturing companies worldwide now and in the
10 United States installing these rather elaborate systems, and
11 when you do that, when you actually sterilize the
12 environment in which the filling of the vials takes place,
13 the failure rate is more like 1 in 100,000 than 1 in 1,000,
14 so it actually makes a big difference.

15 It tells you what people do to a filling
16 operation. I tend to agree with you. I think there is some
17 sort of over-reliance on media fills because there is
18 misunderstanding that it is actually measuring sterility
19 assurance, which it does not.

20 DR. JUHL: I guess you need to use the
21 preservative-free broth.

22 DR. JUHL: Other comments?

23 MR. RUSHO: Oh, yes, I have got several. On the
24 in-process revision, one of the things that I checked, one
25 of the examples here is to make a simulated epidural

1 injection using lactose and 5 percent dextrose in water. I
2 think that should be stricken. I talked with our Acute Pain
3 Service. They have never heard of making an epidural with 5
4 percent dextrose. It is always saline, and it is always
5 adjusted for isotonicity.

6 There are a couple of points once again on the
7 settling plates. I don't see the validity of that.
8 Infection Control, I have talked with our epidemiologists at
9 great length. They have stopped using settling plates in
10 the 1970s. The use of rodac plates on the surface, we know
11 the surface of the laminar flow hood is contaminated. I
12 mean that is good as a training tool to show new employees
13 that the surface is contaminated, but does that really do
14 any good to see if there is growth there. It is treated as
15 a contaminated surface.

16 So, I would question whether or not those things
17 should be in there.

18 I think there should be more material on
19 procedures, such as using dry-heat sterilized beakers.
20 Dry-heat sterilization is not even discussed in this
21 chapter. It talks about autoclaves, steam under pressure.

22 I think dry-heat sterilization is -- you know,
23 Larry talks about glycerine -- we make 100 percent
24 glycerine, and that has to be dry-heat sterilized.
25 Progesterone and oil is dry-heat sterilized.

1 That is a higher risk operation because you have a
2 final aseptic putting the stopper in, in the vial. It is a
3 very high risk operation.

4 One of the things that I haven't seen in this
5 chapter -- and I can't remember where I read it -- but when
6 people use filter sterilization, especially if they are
7 filling several vials with that filter, if you are going to
8 test one, you test the final vial, not the first vial, not a
9 random sampling, because the pores are not all 0.2 micron.
10 There is a variation there, and the probability is the
11 smaller pores will be filled first, leaving the larger ones
12 there, and the contamination there.

13 So, there needs to be a little bit more in there
14 about how people go about it, because most of the
15 pharmacists don't have the knowledge base here, and if this
16 chapter is going to be mandatory, we need to have that
17 material in there.

18 DR. JUHL: Some good practical tips for
19 consideration in the revision. Thank you.

20 Other comments?

21 Let me conclude with an observation for today. We
22 have heard discussion of multiple dose inhalers and patches,
23 and we have heard the extreme difficulty and the number of
24 factors that are associated with the production of these
25 primarily from an industrial perspective, and it has

1 convinced us that we would not recommend that a mere mortal
2 attempt these types of things.

3 I would like to remind you that I suspect that
4 were he allowed the time, Dr. Peck could provide us with a
5 lecture on suspensions and capsules, citing an equal number
6 of factors and complications in the fine art of making
7 suspensions and capsules that would lead us to believe that
8 we wouldn't want to do those either, but we, as of
9 tradition, have accepted the compounding of capsules and
10 suspensions, not because they meet those standards, but
11 because they are better than nothing at all in those
12 instances where a patient is not suitably served by a
13 commercially available product, which is I guess my ongoing
14 bias that when a commercially available product is suitable
15 for a patient, that ought to be used.

16 I think we have had a good demonstration today of
17 why that rule ought to be the rule of thumb that is
18 followed.

19 I can see I have attracted some interest in Dr.
20 Peck to comment. Go ahead.

21 DR. PECK: It would be difficult to discuss
22 capsules, and not having a compounding pharmacist prepare
23 capsules. I think that has been with us for so many years,
24 and all pharmacists have some feeling and experience for
25 that.

1 We may have some thoughts about suspensions and
2 what could or could not happen with suspensions, but I am
3 not aware of any systems that are objectionable as far as
4 compounding is concerned, but there could be.

5 DR. JUHL: I remember having about a semester-long
6 course on all the things that can go wrong with the
7 suspension, and then having to go to the lab and finding out
8 I could do that and make them go wrong.

9 DR. PECK: Well, the microbiologist could help us
10 in suspensions because that is, as you know, an inherent
11 problem with those systems. But capsules, we put our arms
12 and shoulders onto them to solve certain problems.

13 DR. JUHL: But there are interactions with
14 excipients, there are interactions with the capsule. There
15 is the absorption of water. There is all those kinds of
16 things that could enter in, as well.

17 DR. PECK: We are dealing with the gelatin
18 interaction for the last several years, and the FDA
19 committee is still in session on that.

20 DR. JUHL: Other final comments?

21 [No response.]

22 DR. JUHL: We will then reconvene at 8:30 promptly
23 tomorrow morning, and try and conclude our business
24 hopefully before noon.

25 We are adjourned.

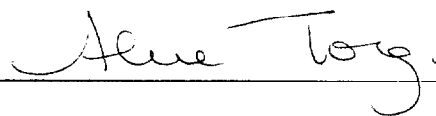
1 [Whereupon, at 4:15 p.m., the proceedings were
2 recessed to be resumed at 8:30 a.m., Friday, July 13, 2000.]

3

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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.

A handwritten signature in cursive script that reads "Alice Toigo". The signature is written above a horizontal line.

ALICE TOIGO

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