

Dr. Samuel Doppelt, President, American Association of Tissue Banks, March 15, 2002 for the Food And Drug Administration Blood Products Advisory Committee

Then I just wanted to add one comment that Dr. Simon -- in response to Dr. Simon. The AATB does have standards, and the FDA has regulations in terms of procedures for processing. In 1996 we had required in our standards that you shall, must, get pre-processing cultures.

There was perhaps some overconfidence that the final cultures and the processing of decontamination and washing and so forth would eliminate virtually everything and that it would be appropriate to change that to "you should" obtain pre-processing cultures, but you still have to get final cultures.

Now Dr. Kainer has pointed out that there are, obviously, some faults with that, because of issues of bacteriostasis. We have since gone back and had the Task Force on Sentinel Events and the Standards Committee review all of this, and it was their recommendation, and the Board approved it, to go back and insist that all banks, all accredited banks, have pre-processing cultures.

Nevertheless, the AATB had done a review of the banks that were accredited, and they had reviewed 50. 45 or 46 out of the 50 still continued all these years -- I mean since '96 -- still continued to do pre-processing cultures. So the majority of tissue that was processed and distributed had always had pre-processing cultures.