

99N-0386

Global Blood Collection Pioneer

Early 1970's - Plateletpheresis

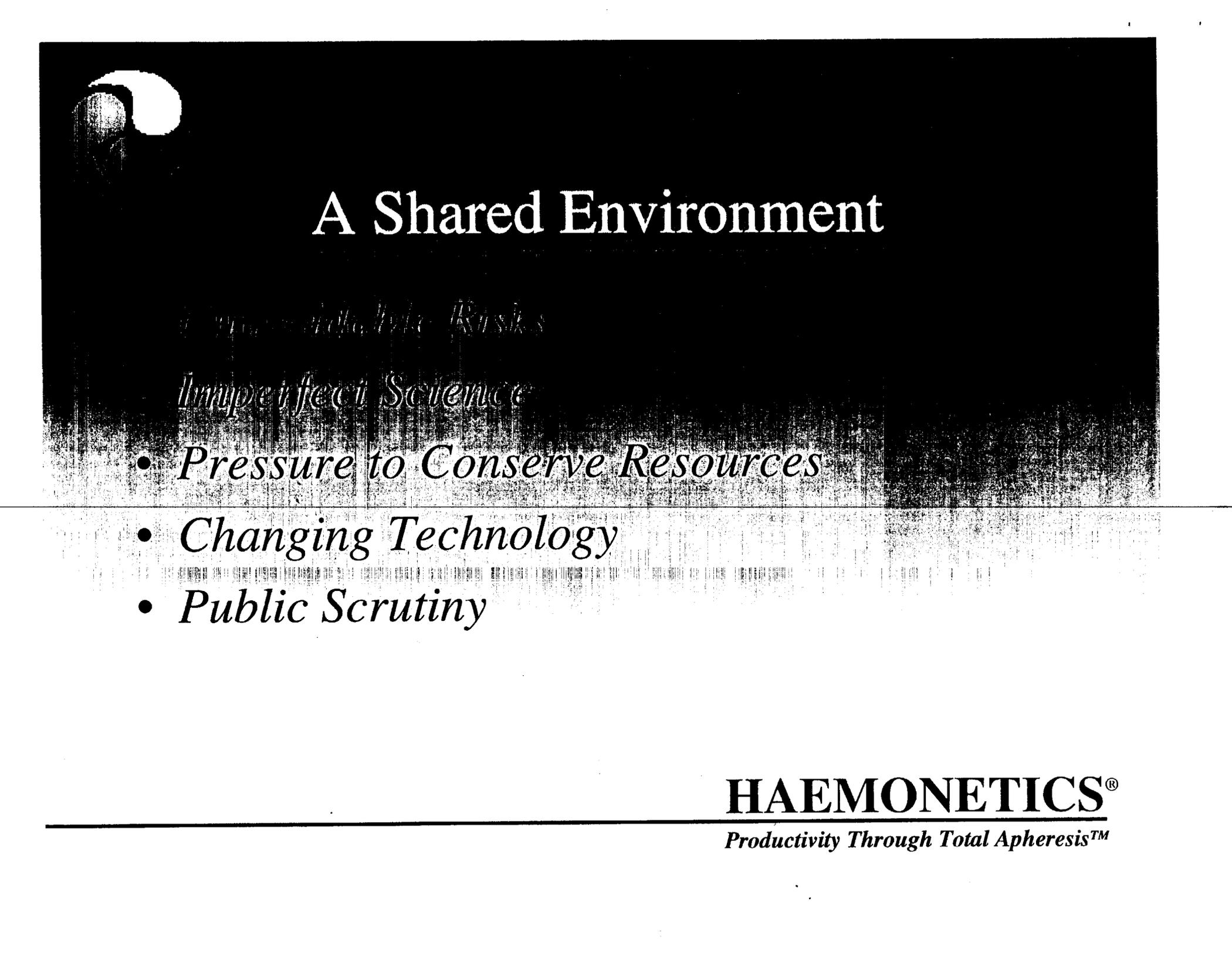
1970's - Surgical Blood Salvage and Autotransfusion

- *1980's - Automated Plasmapheresis*
- *1990's - Two-Unit RBC Collections*
- *1999-2000 - NDA's for anticoagulants*

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TS4



A Shared Environment

Unpredictable Risks

Imperfect Science

- *Pressure to Conserve Resources*
- *Changing Technology*
- *Public Scrutiny*

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Shared Goals

Safe Medical Devices

- *Devices That Perform as Expected*
- *Improve Health/Medical Care*
- *Improve Blood Safety and Availability*
- *Operate in a Cost Effective Manner*
- *Make it easy to do business with us*

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Regulatory Layers

Home Medical Devices

- Premarket clearance*
- Post market changes*
- Inspections*
- MDR*

Home Medical Consumables

- Premarket clearance*
- Post market changes*
- Error Reports*
- MedWatch & MDR*
- Annual Reports*
- Inspections*

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Science

Less formal communication between scientists

*Visiting programs for scientists in public
and private sectors.*

- *Public access to FDA/Industry Task Force
or liaison meetings.*
- *Advisory Committees*

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Resources

- *Global Process & Harmonization*
- *Integration of medical device/drug clearances & related blood product BLA*
- *Maximum use of special 510k, annual reports, comparability protocols.*
- *Third party reviews*

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Risk

What are the main elements of risk?

Industry's Responsibility

- *Physician's Duty*

- *Patient's Right*

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GOOD MORNING. MY NAME IS LISA LOPEZ AND I AM VICE PRESIDENT AND GENERAL COUNSEL OF HAEMONETICS CORPORATION, A MEDICAL DEVICE FIRM BORN IN BOSTON OVER 25 YEARS AGO. WE ARE NOW A GLOBAL COMPANY WITH CUSTOMERS THROUGHOUT THE US, EUROPE AND ASIA, BUT OUR HEADQUARTERS IS HERE, A LANDMARK ON ROUTE 128 IN BRAINTREE.

HAEMONETICS HAS ALWAYS BEEN ASSOCIATED WITH INVENTION AND INOVATION, PIONEERING THE COLLECTION OF SPECIFIC BLOOD COMPONENTS FROM HEALTHY DONORS IN THE 1970'S AND 80'S, AND PIONEERING BLOOD SALVAGE AND RE-INFUSION FOR PATIENTS IN HOSPITAL OPERATING ROOMS. MOST RECENTLY, WE INTRODUCED A SYSTEM FOR THE SAFE COLLECTION OF 2 UNITS OF RED CELLS FOR TRANSFUSION FROM A SINGLE DONOR. THIS ADVANCE WILL IMPROVE BOTH THE AVAILABILITY OF BLOOD AND THE SAFETY OF TRANSFUSION MEDICINE PRACTICES.

HAEMONETICS IS GRATEFUL FOR THIS OPPORTUNITY TO TALK WITH CBER'S LEADERSHIP.

WE ARE ENCOURAGED BY THE RESPONSES FDA HAS MADE TO THE FDA MODERNIZATION ACT. WE BELIEVE THAT THE BENEFITS OF THESE FUNDAMENTAL CHANGES IN THE WAY YOU INTERACT WITH INDUSTRY WILL REAP BENEFITS FOR THE AGENCY, INDUSTRY, AND MOST IMPORTANT, THE PUBLIC.

THE QUESTIONS POSED FOR THIS MEETING CENTER AROUND THE CHALLENGING ENVIRONMENT THAT WE SHARE WITH YOU AT FDA: ONE OF UNAVOIDABLE RISK AND IMPERFECT SCIENCE. ONE WHERE THE PRESSURES OF COST CONTAINMENT, COMPETITION, AND TECHNOLOGY ARE FUNDAMENTALLY ALTERING THE ARCHITECTURE OF OUR BLOOD PRODUCTS DELIVERY SYSTEMS.

IN ADDITION TO SHARING ENVIRONMENTAL CHALLENGES, WE ALSO SHARE A PUBLIC THAT IS QUICK TO FIND FAULT AND SLOW TO FORGIVE. PERHAPS BECAUSE OF THESE CHALLENGES, INDUSTRY AND FDA ARE MOTIVATED BY MANY OF THE SAME GOALS.

- 1. THE DESIRE TO MAKE DEVICES AS SAFE AS POSSIBLE FOR PATIENTS, DONORS, AND OPERATORS;
- 2. THE NEED TO MAKE SURE THAT OUR PRODUCTS MEET CUSTOMER NEEDS AND EXPECTATIONS,
- 3. THE DESIRE TO MAKE TO WORLD A BETTER PLACE AND

•4. THE NEED TO IMPROVE OPERATIONS BY ADOPTING "BEST PRACTICES" TO MEET EXPECTATIONS OF OUR SHAREHOLDERS, OR IN FDA'S CASE, ITS STAKEHOLDERS.

THESE SHARED GOALS ARE TOO OFTEN OVERLOOKED BY THE MEDIA AND EXTERNAL CONSTITUENCIES THAT WE ALSO SHARE -- PATIENTS AND THEIR FAMILIES, BLOOD OVERSIGHT BODIES, AND OTHER ARMS OF FEDERAL AND STATE GOVERNMENTS. BECAUSE WE HAVE SHARED CONSTITUENCIES, WE WILL IMPROVE OUR COMMUNICATIONS WITH THEM IF WE SEND A CONSISTENT MESSAGE -- ONE THAT SAYS "WE'RE DOING THE BEST WE CAN BUT WE'RE NOT PERFECT." WE MUST BE PREPARED TO SAY WE'RE SORRY WHEN WE MAKE A MISTAKE AND AVOID SETTING UNREALISTIC "ZERO RISK" EXPECTATIONS FOR OUR PRODUCTS AND SERVICES.

BECAUSE SEVERAL OF THE QUESTIONS FOR THIS MEETING INVOLVE FDA'S RESPONSIBILITIES THROUGHOUT A PRODUCT'S LIFE CYCLE, I'D LIKE TO TAKE A FEW MOMENTS TO EXPLAIN THE UNIQUE ENVIRONMENT IN WHICH HAEMONETICS OPERATES IN THE US, WITH OUR LICENSED BLOOD/PLASMA CUSTOMERS.

THE BULLETS AFTER "PREMARKET CLEARANCE" LIST THE CHANNELS OF COMMUNICATION WITH FDA THAT ALREADY EXIST FOR HAEMONETICS AND OUR CUSTOMERS DURING A PRODUCT'S LIFE CYCLE. THE INFORMATION GATHERED VIA THESE MECHANISMS PROVIDES AN IMPORTANT RESOURCE FOR SCIENTIFIC STAFF INVOLVED IN RISK BASED DECISIONMAKING. PARENTHETICALLY, WE HOPE THAT THIS INFORMATION IS AVAILABLE TO THE SCIENTISTS WHO COULD BENEFIT FROM THE EXPOSURE -- AND NOT JUST LIMITED TO THE ADMINISTRATIVE STAFF CHARGED WITH ROUTINE REVIEW.

BEFORE LEAVING THIS SLIDE, I WANT TO MENTION THE TWO-TIER PREMARKET APPROVAL PROCESS THAT CURRENTLY EXISTS FOR HAEMONETICS AND OUR LICENSED BLOOD/PLASMA CUSTOMERS. IT IS UNIQUE IN THE US PUBLIC HEALTH REGULATORY SCHEME AND IN THE WORLD.

ALTHOUGH DEVICE OR DRUG MANUFACTURERS IN OTHER MEDICAL FIELDS NEED ONLY OBTAIN PREMARKET CLEARANCE TO INTRODUCE THEIR PRODUCTS IN THE US, THIS SCHEME APPLIES TO HAEMONETICS ONLY INsofar AS OUR SALE OF INSTRUMENTS TO UNLICENSED CUSTOMERS, FOR EXAMPLE A HOSPITAL CUSTOMER. BUT THE USE OF THE SAME NEW DEVICES AND DRUGS IN LICENSED BLOOD OR PLASMA FACILITIES IS ROUTINELY SADDLED WITH A SECOND APPLICATION REVIEW, INSPECTION, AND APPROVAL PROCESS.

THIS MEANS THAT EVEN AFTER A 510(K) REVIEW PROCESS WHICH CAN TAKE UP TO SEVERAL YEARS FOR A DEVICE, AND LONGER FOR NDA REVIEW OF A NEW ANTICOAGULANT SOLUTION, THERE IS A FURTHER

DELAY FOR A YEAR OR MORE IN IMPLEMENTATION OF NEW TECHNOLOGIES BY LICENSED USERS. THIS TRANSLATES TO UP TO THREE YEARS BETWEEN THE TIME NEW TECHNOLOGY HAS COMPLETED THE R&D CYCLE, AND THE TIME IT MAY BE UTILIZED BY USERS.

IN BALANCING THE PUBLIC POLICY CONSIDERATIONS OF REGULATING BLOOD IN THE WORLD AFTER AIDS, WE MUST ACKNOWLEDGE THAT THE RISK OF INDECISION, OR AN UNDULY DELAYED DECISION MAY BE JUST AS DANGEROUS TO THE PUBLIC HEALTH AS A POOR DECISION. GIVEN THE WORLD WIDE NEED FOR SAFER, HIGHER QUALITY, SUFFICIENTLY AVAILABLE BLOOD PRODUCTS, INDUSTRY SHOULD BE ENCOURAGED TO DIRECT ITS ENGINEERS AND SCIENTISTS TO BE MORE INNOVATIVE, MORE CREATIVE, AND LESS CONSTRAINED BY CONVENTIONAL APPROACHES TO PRODUCT DESIGN. FOR THESE EFFORTS TO RESULT IN THE KINDS OF EXTRAORDINARY PUBLIC HEALTH IMPROVEMENTS DEMANDED BY THE PUBLIC'S SENSE OF URGENCY ABOUT BLOOD SAFETY AND AVAILABILITY, THEY MUST BE COUPLED WITH LESS BURDENSOME PATHS TO REGULATORY APPROVAL.

A GOOD EXAMPLE WAS THE BURDENSOME APPROACHES FOR BLOOD TESTING WHICH WERE USED SUCCESSFULLY BY CBER WHEN IT WAS RECOGNIZED THAT THE PUBLIC'S URGENCY FOR IMPROVEMENTS DEMANDED NO LESS. SIMILARLY, LESS BURDENSOME APPROACHES FOR BLOOD COLLECTION EQUIPMENT USERS COULD SAVE FDA RESOURCES WITHOUT COMPROMISING PUBLIC HEALTH. LET'S REMEMBER THAT AUTOMATED BLOOD COLLECTION DEVICES HAVE HAD A GOOD TRACK RECORD FOR OVER 25 YEARS.

HAEMONETICS WOULD WELCOME THE OPPORTUNITY TO COMMUNICATE WITH FDA SCIENTISTS IN A LESS FORMAL MANNER--OUTSIDE THE CONTEXT OF APPLICATION REVIEW, INSPECTIONS, OR ENFORCEMENT ACTIONS.

WE WOULD BE WILLING TO HOST SCIENTIFIC VISITORS FROM FDA OR COME TO FDA, TO DEMONSTRATE HAEMONETICS' TECHNOLOGIES, AND TO ASSIST IN GENERAL TRAINING AND EXCHANGES OF IDEAS AND EXPERTISE. IN ADDITION TO IMPROVING THE SCIENTIFIC KNOWLEDGE BASE UPON WHICH FDA DECISIONS ARE MADE, WE BELIEVE THAT SUCH INTERACTION WOULD PREVENT MISUNDERSTANDINGS, REDUCE THE NUMBER OF CYCLES DURING APPLICATION REVIEW, AND FOSTER A MORE CONSTRUCTIVE CLIMATE FOR PROBLEM SOLVING WHEN NECESSARY.

FDA'S EFFORTS TOWARD HARMONIZATION WITH REGULATORY AUTHORITIES IN OTHER COUNTRIES HAVE BEEN ENCOURAGING. WE HOPE THAT THEY WILL CONTINUE UNTIL A SINGLE DOSSIER IS ACCEPTED WORLD-WIDE.

SIGNS OF INTERNAL HARMONIZATION BETWEEN CDRH AND CBER AS EXHIBITED BY CBER'S DEVICE ACTION PLAN, AND MONDAY'S FEDERAL REGISTER NOTICE ARE ALSO ENCOURAGING. IT HAS ALSO BEEN GRATIFYING TO SEE COMMENTS FROM THE STAKEHOLDERS MEETINGS LAST FALL NOW BEING INTEGRATED INTO WORKING GROUPS AT CBER. EVERYONE WILL BENEFIT FROM THESE PLANS.

I SPOKE EARLIER ABOUT LAYERS OF REGULATION -- WHILE IT MAY NOT BE POSSIBLE TO ELIMINATE TOTALLY THE REDUNDANCIES IN THE PREMARKET CLEARANCE OF BLOOD TECHNOLOGIES AND THE BLOOD PRODUCTS THEY MANUFACTURE, FDA COULD MAKE SOME APPROVAL ROUTES LESS BURDENSOME FOR ITSELF AND INDUSTRY BY REEXAMINING TRADITIONAL APPROACHES TO REGULATION WITH AN EYE TOWARD INTEGRATING SOME PREMARKET APPROVAL PROCESSES AND STREAMLINING DATA SUBMISSION REQUIREMENTS WHERE RISK IS LOW AND TRACK RECORDS HAVE BEEN ESTABLISHED.

THIRD PARTY REVIEWS ARE BEING USED BY CDRH BUT HAVE NOT BEEN TRIED IN THE "BLOOD" DEVICE SECTOR, AND COULD BE.

FINALLY, THANK YOU, FDA, FOR BEGINNING TO MOVE AWAY FROM "ZERO RISK" RHETORIC. PARTICULARLY FOR THOSE OF US IN THE BLOOD SECTOR, THE DECISION PARALYSIS THAT RESULTED FROM THOSE YEARS IS JUST BEGINNING TO SUBSIDE. NOW IT'S JUST DECISION ANXIETY. PERHAPS NOW WE CAN MOVE FORWARD TO EDUCATE THE PUBLIC AND OTHER EXTERNAL CONSTITUENTS ABOUT PATIENT DECISION MAKING AND RISK ACCEPTANCE.

PROMOTING MEDIA STORIES ABOUT RISK, EVEN TV SHOW STORY LINES (AS IS BEING PLANNED FOR THE HEPATITIS C EDUCATION CAMPAIGN) WOULD REAP BENEFITS. BUT THESE EFFORTS MUST BE ONGOING. MAYBE WE'LL EVEN GET THROUGH TO THE PHYSICIANS AND LAWYERS IN THE PROCESS.

THANK YOU FOR THIS OPPORTUNITY TO SPEAK TODAY, AND FOR THE IMPROVED COMMUNICATIONS WE HAVE SEEN VIA THE INTERNET AND THESE PUBLIC MEETINGS. WE HOPE THAT THESE TYPES OF COMMUNICATIONS WILL CONTINUE. NOW THAT WE HAVE ACTION PLANS WITHIN CBER FOR BOTH BLOOD AND DEVICES, WE LOOK FORWARD TO CONTINUED PROGRESS REPORTS ON THEIR IMPLEMENTATION. A RETURN TO PRODUCT APPROVALS WITHIN STATUTORILY MANDATED TIMELINES IS NOT A NOBLE GOAL. IT'S THE LAW. AND A PUBLIC POLICY IMPERATIVE.