Final Report

Summary of the *Hospital Beds and the Vulnerable Patient* Meeting
February 24-25, 2000
Stuart, Florida

On February 24-25, representatives from Federal government, private industry, consumer groups and professional organizations, assembled for the second meeting of the Hospital Bed Working Group in Stuart, Florida to address concerns related to hospital bed use and vulnerable patients. This group first met on April 26 and 27, 1999 at the Department of Health and Human Services in Washington, DC. At that time, seven topic areas surfaced as the most important issues to reduce the risk of entrapment and injuries related to hospital beds, with a specific focus on siderails/bedrails.

Participants joined one or more of the seven issue groups, which focused on:

- Reconciliation of regulatory definitions and requirements related to hospital beds;
- Developing a new universal standard of care for the use of bedrails;
- Assessment of legacy equipment now in use and creation of suitable options for continued use of this older equipment;
- Development of new design guidance to improve safety in the bed environment;
- Evaluation of this guidance;
- Enhancement of scientific knowledge on the bed environment; and
- Outreach efforts focused on improvement in patient's safety concerning beds and bedrails.

Day 1 - February 24, 2000

The meeting opened with welcomes by Dr. Larry Kessler and Dr. Lireka Joseph of the FDA's Center for Devices and Radiological Health. They cited the dedication and remarkable efforts of this workgroup which has provided valuable insights towards improving patient safety. They reminded us of the common bond that brought us together, that is, our desire to make a difference! They mentioned that each of us has made unique and positive contributions to this effort and we were challenged to continue the fine work.

The presentations began with the medical research of Dr. Richard Neufeld and Ms. Joan Dunbar, from New York's Jewish Home and Hospital. The results of their new work examined the injuries associated with hospital beds. Next, Dr. Audrey Nelson and Dr. Stephanie Hoffman from the U.S. Department of Veterans Affairs and Denis Roy, from the Medical Devices Bureau, Health Canada presented their respective initiatives in this area.

The remainder of the day was devoted to presentations by the issue group leaders. Each group had made substantial progress in the 10 months since the first meeting. At the conclusion of the day, Julie Braun, J.D., Chair-Elect of the American Bar Association Medicine and Law Committee addressed the group and presented several interesting opportunities for the group to consider.

The following brief narratives summarize the presentations of Day 1.

Richard Neufeld, M.D., Jewish Home and Hospital

Dr. Neufeld presented his research topic "Bed-related Incidents and Injuries Among Nursing Home Residents and Staff". He concluded that residents in the study bed had significantly more bed-related incidents, but only one third as many serious injuries requiring medical attention. Also staff had significantly fewer and less serious injuries when working with the study bed compared to the control bed. The study bed was designed with smaller rails specifically developed for use in nursing homes.

Joan Dunbar, M.S.W., M.B.A., Jewish Home and Hospital

Ms. Dunbar presented her research topic "Siderails and the Attitudes of Nursing Home Residents, their Families and Staff". Several conclusions were reached including: 1) siderails do not prevent residents from getting out of bed, 2) staff were divided as to whether siderails posed an increased risk to safety and injuries and 3) many staff, residents and family misunderstand the family's role in requesting siderails.

Audrey Nelson, R.N., Ph.D. and Stephanie Hoffman, R.N., Ph.D., Veterans Administration Hospitals
Drs. Nelson and Hoffman briefed the workgroup on some of the areas of research at the Veterans Administration (VA) Hospitals designed to increase patient safety. These included:

- Assessment of the biomechanics of horizontal and vertical patient transfers with a variety of equipment (wheelchairs, stretchers, beds, lifts, etc.). Side rail and bed configurations are very important factors in the success of a transfer on both the patient and caregiver.
- A three-year study identifying 12 high-risk tasks which predispose caregivers to injuries. Several of these tasks were related to hospital beds. The VA has redesigned these tasks and is in the process of evaluating the redesigned tasks to improve safety. Bed height and side rail locations are factors.
- Development of a National Veterans Administration Resource Guide on safe patient equipment for VA clinicians and purchasers.
- Veterans Administration's technology division is developing a prototype of a safe patient room of the future, which can be adapted to all patient settings.
- Piloting an effort that looks to change bedrail use. The process of change is compared between supportive units and resistive units. Interventions that are effective in making those changes are identified.
- Creation of an adverse event system for reporting errors in the VA that is more comprehensive and less blame related.

Denis Roy, P. Eng., Medical Devices Bureau, Health Canada

Mr. Roy's presentation, "The Need for Safety Standards for Institutional Beds and Siderails" included data on bed incidences in Canada and the USA. He looked at why standards in this area are necessary and described the Canadian draft standards and test methods.

Julie Braun, J.D., LL.M., Chair-Elect, American Bar Association Medicine and Law Committee

Ms. Braun briefly described several projects she is working on examining the legal and medical aspects of physical restraints and hospital bed siderails. She distributed copies of pre-publication manuscripts that she and Dr. Capezuti coauthored which exam siderails and their legal liability in nursing homes. She also offered to assist in reviewing legal databases and to look at case law studies to address the liability surrounding bed siderail use and the associated risk management issues. Lastly, Ms. Braun described several outreach vehicles that might be useful to the workgroup in disseminating medical/legal information. Mrs. Braun offered the conference services of the Health Law Program, College of Law, DePaul University as host of the next working group meeting.

Issue Leader Presentations:

Issue 1: Consistency Among Regulatory Bodies
Jeannie Miller, R.N., B.S.N., and Cindy Hake, R.N., M.S., Health Care Financing Administration

Ms. Hake discussed how HCFA and the FDA defined physical restraints including bed rails. A draft HCFA/FDA letter stating each agency's position on physical restraints was distributed. Instructions were given to attendees to review the letter. The letter was discussed and comments were provided on Day 2. See Issue Group 1 Summary Report.

Ms. Miller discussed surveyor inconsistency in all facilities and HCFA's effort to reduce this variation through enhanced surveyor training, program memoranda, etc. HCFA's reporting requirement for restraint-related deaths and injuries in hospitals and long term care facilities was reviewed. She also explained aspects of the relationships between HCFA and accrediting organizations.

JCAHO joined us by phone to discuss their position on siderails as physical restraints. Their position was consistent with HCFA's.

Issue 2: Universal Standards of Care
Presenter: Janet Myder, M.P.A. American Health Care Association

Ms. Myder discussed the draft of a paper prepared by her Issue Group. The paper entitled Universal Clinical Guidance for the Assessment for Use and Implementation of Hospital Bed Siderails in Hospitals, Long Term Care Facilities and Home Health Settings. This standard of care is based on clinical assessment of individual patients' needs. The guidelines include in part, guiding principles, assumptions made, policy considerations and risk intervention. Attendees were asked to read the draft guidelines for discussion the next day.

Issues 3 and 5B: Evidence Based Equipment Design and **Legacy Equipment: Creating Suitable Options for Use of Older Equipment.**
Presenter: Lance Lockwood, Hill-Rom Company

Mr. Lockwood informed the workgroup that Issue Groups 3 and 5B have narrowed their scope to focus on 1) bed system component interface issues and 2) life threatening entrapments (not falls or restraints). He mentioned that his issue group identified 16 objectives they wish to meet, (e.g. develop a system to assure compatible bed components) and 10 recommendations they wish to offer, (e.g. manufacturer's should perform New Product Development (NPD) Component Risk Assessments on critical components.) Additionally, 10 items were identified that still need to be explored, (e.g. chest depth and neck control dimensions are yet to be finalized).

Issue 4: Evaluation of Bedrail Guidance
Presenter: Dick Sawyer, Ph.D., Food and Drug Administration

Dr. Sawyer presented various issues that should be considered in evaluating the Evidence-Based Equipment Design guidance being developed by Issue group 3. Some of the issues discussed include:

- competitive and creative aspects of design,
- variability of the equipment, patients and device use,
- extent of the guidance (e.g. rails, mattresses, controls, latches, crossbars, etc),
- impact on entrapment versus falls,
- user and patient acceptance, and
- impact on existing regulations.

Dr. Sawyer recommended a two part evaluation: the first part being an "internal" evaluation by the Working Group members at their institutions to unearth major problems, if any; and a second level "external" evaluation of employee health care facilities recruited through healthcare organizations and manufacturers.

Issue 5A: Legacy Equipment: Identify Hazardous Older Equipment
Presenter: Mark Bruley, ECRI

Surveys were designed and sent to health care facilities (hospitals and nursing homes) and manufacturers to identify the types of medical beds, siderails and mattresses (bed systems) currently in use in U.S. The survey was sent to approximately 3200 hospitals, 10,000 long-term care facilities and 200 manufacturers. The final report is to be completed in late April 2000.

Issue 6: Enhance Our Scientific Knowledge To Improve the Clinical Effectiveness and Safety of Bed Systems.
Presenters: Georgene Saliba, R.N., B.S.N., F.A.S.H.R.M., American Society for Healthcare Risk Management and Liz Capezuti, Ph.D., R.N., C.R.N.P., University of Pennsylvania

Ms. Saliba identified numerous data sources the group could potentially study to enhance its scientific knowledge of safety and effectiveness of bed systems. Many of these data sources; however, had inherent limitations to their use in extracting information. Ms. Saliba offered several potential solutions to overcoming these limitations including contacting reporters to collect individual event data, revising existing forms or developing a new reporting form, and encouraging more consistent reporting between State reporting systems. Dr. Capezuti provided a handout of side rail and related references from the medical literature.

Issue 7: Create Uniform Educational Outreach
Presenter: Beryl Goldman, R.N., M.S., N.H.A., Kendal Corporation

Ms. Goldman's presentation addressed the topic of information dissemination. Among issues to be considered under this topic were:

- Who needs this information and in what format
- What modes of distribution would be most effective and
- What steps should be followed next

Day 2 – February 25, 2000

The morning of Day 2 was spent in breakout groups furthering the work of the various issues groups. It was decided that the work of several of the issue groups overlapped and that it would be more efficient if those groups were combined into a single unified issue group. Consequently, the larger workgroup has collapsed the work of issue groups 3, 4, 5A and 5B into a single group and will be referred to as Issue Group 3, 4, 5. Following the breakout work sessions, issue leaders presented their group's report. The reports are provided as attachments to these minutes.

Towards the end of the meeting several broader issues were discussed which seemed to have implications on the entire bedrail project. They are summarized below:

- **FUNDING**

The issue of funding comes up in several different ways:

1. Justifying our time and effort to our employers and
2. Funding our workgroup's various efforts (educational outreach materials; research; website, etc.)

The workgroup discussed the need to look for potential sources of funds. ECRI and FDA will look into sources of funding. Some suggested sources include the Agency for Healthcare Research and Quality (AHRQ), (formerly known as the Agency for Healthcare Policy and Research) and the Quality Interagency Coordination (QuIC) Task Force. AHRQ is a federal agency that supports research into the causes of medical errors and how to prevent them. QuIC is an interagency task force to improve the care delivered or purchased by federal agencies and to develop the infrastructure needed to improve the health care system. Both AHRQ and QuIC have received funding to address adverse incidents associated with medical error.

- **IDENTITY/FORMALIZED WORKING AGREEMENTS**

The question of "Who Are We?" was discussed. In the past year, we have done an outstanding job of combining our talents and resources to look at ways to improve hospital bed safety. We questioned whether we are now at a point where our workgroup should be formally identified.

One possible vehicle discussed at the meeting to achieve this was the CRADA or Cooperative Research and Development Agreement. It is believed that the CRADA or similar vehicle could be used to give recognition and identification to our workgroup which to date has been operating simply as a group of individuals. The CRADA or similar vehicle will lay down a framework and rules that will permit government and non-governmental agencies to work together and not worry about conflict of interest issues. FDA agreed to research for the workgroup the pros and cons of using a CRADA to identify our workgroup. FDA will present this to the group for acceptance or rejection. A group consisting of Larry Kessler, Mark Bruley and Susan Meadows will look into this issue of identity and formal recognition.

Following the meeting, FDA learned that the CRADA may not be the best mechanism to use for the type of activities involved in the bedrails project. Generally, CRADA's are used for research projects. An alternative mechanism that has been recommended is a federal Co-sponsorship Agreement (see attached sample format). Under this agreement, the major parties list what they are bringing to the effort including major responsibilities, resources, and contracts related to the activities of the workgroup. No funds are exchanged under this agreement and it is effective as soon as the parties enact it with signatures. It has been suggested that this agreement be between FDA and, at most, two other parties. This would necessitate the workgroup to organize itself under lead organizations that would sign the agreement. Individual companies and organizations would be listed as contributors or collaborators under the lead organizations. Comments are requested on this approach.

- **FURTHER PARTNERING**

Do we have the right players? Who do we need to add as our work expands? We felt we needed to evaluate the existing groups participating and draft a high priority list of a few groups that are not represented whose voice we need. We do not want to duplicate representation. Large group buy-in is especially critical when we move from workgroups to product implementation where support of others is needed. Once we get all the various activities going we need members who will take an active role in outreach. We need groups that will train others, or sponsor regional meetings to bring training to clinicians. We will ask each issue group to craft a mission statement.

Additional groups or types of expertise that may be desirable include:
- More physician involvement
- More voice by home health care groups
- National Consumers' League

We are seeking active representatives from JCAHO and AARP to join our group.

The workgroup discussed several other groups or organizations that we might consider collaborating with to further our goals. These are:

- The Agency for Healthcare Research and Quality (AHRQ) and Quality Interagency Coordination Task Force (QuIC).
- The National Patient Safety Foundation, a group formed by the American Medical Association to address medical error and patient safety.
- A standards organization such as American National Standards Institute (ANSI), International Electrotechnical Commission (IEC), Association for the Advancement of Medical Instrumentation (AAMI), or American Society for Testing and Materials (ASTM) to promulgate the dimensional recommendations for rails that will come out of our workgroup.

Lastly, we briefly discussed how we should handle unsolicited requests from newcomers to join the workgroup. We agreed that we will place new members on a resource contact list that will be available to the workgroup. We will then refer to the resource list and tap new members on an as needed basis.

Issue Group 1 Summary Report
Consistency Among Regulatory Bodies
Jeannie Miller

Group one was charged with drafting a memorandum for public distribution explaining the difference between the HCFA and FDA definitions of restraints. Additionally, we were asked to explore avenues to address differences in interpretations of restraint requirements among surveying organizations (i.e. State survey agencies, JCAHO). Participants on the group represented the government, provider community, manufacturers and associations. The JCAHO participated in the February meeting by telephone and provided their interpretation of restraint requirements, which was similar to HCFA's interpretation.

Following discussion about the memo at the February 2000 meeting, HCFA was asked to make some final revisions to the memo prior to distribution. These revisions include adding information about deemed provider responsibilities and a statement from the FDA supporting HCFA in their role of enforcement.

Following our group meeting in February, we presented the following items to the entire workgroup outlining the future plans for Workgroup 1:

- Asked the FDA to review their current restraint definition and consider a revision that would reflect current practice.

- Asked the FDA to consider requiring re-labeling of devices clearly used as restraints.

- We will add the requested language to the memo and distribute as planned.

There are no future plans for work addressing interpretation differences between surveying entities.

Issue Group 2 Summary Report
Universal Hospital Bed Siderail Guidance
Priscilla Shoemaker

1. Work toward finalizing the "draft" universal guidance, generally applicable across healthcare settings, that addresses the evolving best practices and protocols related to bed safety.
    - Move the guiding principles contained in the current "draft" guidance to the front of the document.
    - Add clinical decision trees specific to each client setting (e.g. hospital, nursing facility and home health).
    - Circulate the "draft" to a broader audience of interested parties for input.

2. Foster a change in healthcare worker behavior consistent with the universal guidance and evolving best practices regarding bed siderails by working with Issue 7 on the development of a curriculum for use in educating medical, nursing and paraprofessional healthcare students, as well as inservice education/training of staff, patients and families.

3. Seek participation in the ongoing development of the clinical guidance from other interested stakeholders, e.g. Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), National League of Nurses (NLN), American Association of Colleges of Nursing (AACN), American Medical Association (AMA) , American Medical Directors Association (AMDA), American Hospital Association (AHA), etc. whose participation is necessary for implementation

4. Collaborate with manufacturers (Issue groups 3/4/5) toward development of safer bed system designs, in particular, the development of new designs for improved alternative assistive devices to replace traditional bed siderails, consistent with a universal clinical siderail guidance.

5. Continue to stress the need for updating the FDA definition of hospital bed siderails as a regulated medical device that comports more with the definition used by HCFA in order to determine a consistent approach to more appropriate and safer use across all healthcare setting and to ensure safer design.

6. Call for collaboration from Federal regulatory agencies and accrediting bodies (i.e. FDA, HCFA, JCAHO, etc.) to lead this initiative and endorse the universal clinical guidance.

Issue Groups 3, 4, and 5 Summary Report
Evidence Based Equipment Design;
Evaluation of New Design Guidance; and
Legacy Equipment: Identifying Hazardous Older Equipment and Creating Suitable Options for Use of Older Equipment,
Lance Lockwood

- Issue Group 3, 4, & 5 – List of what else needs to be done

1. Issue Group 3, 4, and 5 combined for this meeting and identified forty-six (46) activities in process.

- Major Issues That Need Further Assessment

1. Get to yes about our recommendations
2. Internal validation based on the anthropometric data
3. Other groups input (clinical and mattress manufacturers)
4. Field Validation of our recommendations
5. Review the current equipment "food chain"
6. Mesh learning from all other Issue Groups together
7. Review and recommend funding sources for implementation
8. HCFA definition needs to be influenced by the Task Force
9. Solutions need to be cost effective in the context of the care environments we are serving
10. 3mo scope and Implementation methods
11. 6mo scope and Implementation methods
12. Long-term scope and Implementation methods

- Outputs from Today

1. Issue Groups #4 and #5 have decided to join Issue Group #3
2. The list of what we think, of the original Task List, is complete
3. Next Issue Group 3 meeting: Need to see if ANA and AAAHA annual meeting might be convergible with Issue Group 3,4,5 next meeting.
4. Issue Group 2 input about the "at risk" population – Liaison between Issue Group 3,4,5 and Issue Group 2 will be Mary Bias and Mike Chellson
5. Issue Group 3,4,5 Liaison with Issue Group 7 will be Kendra Doyle and Dick Sawyer
6. Get to "yes" on the doctor's orders issue

   Recommendation: Issue Group 3, 4, 5 believe that a healthcare professional must be involved in the decision-making process regarding the use of full length and half-length foot rails.

- Questions Generated by the Above

  - Big Question #1: What's the practicality of our recommendations. Particularly with respect to the impression that the installed base may be viewed as "unsafe"

  - Big Question #2: All of these action items will change the way care is delivered and we will need to validate these impacts as part of our recommendations? What Issue Group (standards of care group Issue Group 2?)

  - Big Question #3: Where's the money to pay for the implementation of our recommendations?

Issue Group 6 Summary Report
Enhancing Our Scientific Knowledge To Improve the Clinical Effectiveness and Safety of Bed Systems
Georgene Saliba

Enhancing our scientific knowledge to improve clinical effectiveness and safety of bed systems

Next steps and discussion:

Designate a research agenda aimed at patient safety
- Who? Key clinical org
- Consensus validation document
- Utilize and/or apply for the funds from the govt. as a result of the IOM study

Creation of clinical guidelines – look at the literature and data and develop expert conclusions RE: Bed Safety
- American Geriatric society

Reporting
- FDA should investigate the feasibility of individual follow-up via phone contact with the source – need to designate one individual for consistency
- Request photo of the bed involved and a description of the event – with measurements, etc
- De-identify the source
- Educational outreach

Consistency
- Nursing homes should be reporting (using) on the SMDA (Safe Medical Device Act) forms and educated and encouraged to do so by the State Dept of Health
- Cooperation between FDA and DOH
- Educating the HCFA surveyors to educate the States Re: reporting

Education
- FDA should publish update of the material/events in a safety bulletin for all healthcare providers- A PROGRESS REPORT ABOUT BEDRAIL SAFETY - Provide the actual physical recommendations for new product design (NPD) and retrofit
  Encourage contact with bed manufacturers for retrofit products
  Stress to Nursing Homes of the requirement to report adverse events to the FDA

Issue Group 7 Summary Report
Creating Uniform Educational Outreach
Beryl Goldman

Targeting Groups for Educational Process (in order of priority)

1. Healthcare Providers (private and public) and Advocates
   - Current health care staff, administrators, and physicians.
     Rationale: Need to convey accurate and consistent information to their constituents
   - Health care students
     Rationale: Need to learn correct information initially, more difficult to unlearn
   - Advocates
     Rationale: Healthcare providers need to work with advocates to develop a common understanding of bedrail dangers and to ensure that the general public, patients and families are informed about the dangers of bedrails and alternatives, and, when appropriate, to bedrail use.

2. Government Agencies
   - Regulators and Payors
     Rationale: a. Need to be up-to-speed about the bed system issues
     b. Develop appropriate, consistent regulations and standards

3. Media
   - Alert public to dangers of bedrails, particularly to certain segments of the population, and changing patient practices

4. General Public, Patients, Families
   - In collaboration with the healthcare providers and advocates, government agencies and media
     Rationale: Need to understand the ramifications of beds and bedrails to develop more realistic expectation of the health care institutions
   - Should be educated to recognize bedrail dangers and limitations and to make informed decisions about patient safety.

5. Legal, judicial system
   - Alert them to the necessary changing requirements

6. Manufacturers
   - Issue 7 group is willing to support group 3/5B with the education necessary to reach the bed/mattress manufacturers but believe group 3/5B is in a better position to get the information to them.

Issue Group 7 Summary Report (continued)

Suggested ways to reach the above mentioned groups.

1. Health care providers, government agencies
    - Offering continuing education credits
    - For students, get accrediting bodies to mandate bed safety in curriculum
    - Develop printed, video, and other materials
    - Presentations at professional meetings
    - Modify Issue 2 paper for professional publications
2. Media
    - Packets of information
3. General Public
    - Personalized article for popular press (ex. Dear Abby, Readers' Digest)
    - Presentations at community programs
    - Make brochures accessible in doctors' offices and healthcare institutions
4. Legal, judicial system
    - Articles in legal publications (ex. DePaul)
    - Presentations at professional meetings

EXAMPLES OF WHAT SHOULD BE INCLUDED IN A CO-SPONSORSHIP AGREEMENT

CO-SPONSORSHIP AGREEMENT
BETWEEN THE
[INSERT NAME(S) OF CO-SPONSOR(S)]
AND THE
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) and the [name of co-sponsor(s)] agree to co-sponsor [name, date and location of the event] according to the terms expressed below:

1. Background

[Provide the following information: (a) the nature and purpose of the event; (b) the identity and background of the co-sponsor(s); (c) the importance of the event to both CDRH and the co-sponsor; (d) the substantive interest and special expertise of the co-sponsor in the subject matter of the event; (e) any other relevant background information that may explain the mutual interest of CDRH and the co-sponsor in working together on the event.]

Co-sponsors:

[Type name(s) and address of co-sponsor(s)]	Food and Drug Administration Center for Devices and Radiological Health 9200 Corporate Blvd. Rockville, MD 20850
Contacts: [Type name, title, address and telephone and fax numbers]	[Type name of CDRH contact] FDA/CDRH (HFZ-) [address] Rockville, MD 20850 telephone number fax number

2. Responsibilities for Developing the Event

[Provide the following information: (a) the respective responsibilities of CDRH and the co-sponsor for developing the substantive aspects of the event, such as the agenda and speakers; (b) the respective responsibilities of CDRH and the co-sponsor for logistics and finances, such as arranging and paying for conference facilities, advertising, food, and any other event expenses. **Note:** this is the core paragraph of the co-sponsorship agreement, and it should reflect as much detail as CDRH and the co-sponsor reasonably can provide.]

A. [Co-sponsor] will be responsible for: [list responsibilities]
B. CDRH will be responsible for: [list responsibilities]

3. Registration Fees and Other Charges

[Provide the following information: (a) state whether the co-sponsor intends to charge registration fees, and, if so, state that the co-sponsor agrees to set a fee no higher than necessary to recover its share of the costs of the event; (b) state whether CDRH and the co-sponsor agree that CDRH employees will be allowed free attendance at the event; (c) state whether the co-sponsor intends to sell educational materials pertaining to the event or transcripts or recordings of the event, and, if so, that the co-sponsor agrees to sell such items at cost.]

4. Independently Sponsored Portions of Event

[Provide the following information: (a) state whether either CDRH or the co-sponsor intends to sponsor any discrete portion of the event independently; (b) describe any separately sponsored portion; (c) state that CDRH resources, including staff, will not be used to develop, promote or otherwise support a portion of the event that is independently sponsored by the co-sponsor, although official announcements and brochures may contain factual references to the schedule of the entire event, including portions sponsored solely by the co-sponsor.]

If none, type 'There are No Independently Sponsored Portions of the Event".

5. Fundraising

[Name of co-sponsor] will make clear, in any solicitation for funds to cover its share of the event costs, that it, not CDRH, is asking for the funds. [Name of co-sponsor] will not imply that CDRH endorses any fundraising activities in connection with the event. [Name of co-sponsor] will make clear to donors that any gift will go solely toward defraying the expenses of [name of co-sponsor], not CDRH.

6. Promotional Activity

[Name of co-sponsor] will not use the event primarily as a vehicle to sell or promote products or services. [Name of co-sponsor] will ensure that any incidental promotional activity does not imply that CDRH endorses any products or services. [Name of co-sponsor] will make reasonable efforts, subject to CDRH review, to segregate any incidental promotional activity from the main activities of the event.

7. Event Publicity and Endorsements

[Name of co-sponsor] will not use the name of CDRH or any of its components, except in factual publicity for the specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Factual publicity shall not imply that the involvement of CDRH in the event serves as an endorsement of the general policies, activities, or products of [co-sponsor]. [Name of co-sponsor] will clear all publicity materials for the event with CDRH to ensure compliance with this paragraph.

8. Records

Records concerning the event shall account fully and accurately for the financial commitments and expenditures of CDRH and [name of co-sponsor]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

9. Public Availability

This co-sponsorship agreement, as well as the financial records described in paragraph 8, shall be publicly available.

10. Co-Sponsorship Guidance

CDRH and [name of co-sponsor] will abide by the legal memorandum of March 20, 1995, "Co-Sponsorship Guidance," issued by HHS's Special Counsel for Ethics.

Approved and Accepted by the [name of co-sponsor]

_____

[name] Date
[title]

Approved and Accepted for the Center for Devices and Radiological Health

_____

David W. Feigal, Jr., M.D., M.P.H. Date
Director

FDA Concurrence

_____

Jenny Slaughter Date
Chief, Ethics and Personnel Security Branch