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The **PRESIDING OFFICER.** The majority leader is recognized.

#### UNANIMOUS-CONSENT AGREEMENT

Mr. MITCHELL. Mr. President, I ask unanimous consent that when the Senate resumes consideration of Calendar No. 333, S. 1504, a bill to authorize appropriations for public broadcasting, it be considered under the following time limitations:

Two hours on the bill, including the committee substitute amendment; that the following amendments, in addition to the committee-reported substitute, be in order in the first degree under the time limitation indicated and not subject to second-degree amendments; with the only other amendments in order being relevant to the bill or the committee substitute amendment, as amended, or, if in the second degree, relevant to the amendment to which they are offered:

Ten minutes on the managers' substitute amendment that will be offered and agreed to prior to any other amendment, to incorporate certain provisions of the House bill (H.R. 2977); with the provision that follow-

ing the adoption of this substitute amendment, the reported substitute as thus amended be treated as original text for the purpose of further amendment;

Ten minutes on the managers' amendment on broad terms and accountability;

Ninety minutes on a Helms amendment to freeze or reduce the funding levels of the bill;

One hour on a Dole amendment with respect to funding for the Independent Television Service [ITVS];

Ten minutes on a Byrd amendment on indecency;

Five minutes on a Bingaman amendment on a report on the establishment of a ready-to-learn channel for preschool children;

Five minutes on a Pressler amendment on a report on using public broadcasting satellite for distance learning;

Thirty minutes on a McConnell amendment—requiring that TV programs funded by the CPB, include with the credits the statement that the CPB "is a private nonprofit corporation created by Congress," or similar language;

That all limitations on time for debate be equally divided and controlled in the usual form; that no motions to recommit be in order; and that following third reading of the bill, all of the following occur without any action or debate: the Commerce Committee be discharged from further consideration of H.R. 2977, the House companion bill, and the Senate proceed to its immediate consideration; that all after the enacting clause be stricken and the text of S. 1504, as amended, be inserted in lieu thereof; the bill be read for the third time, and the Senate proceed to vote on passage of H.R. 2977, as amended; and, that upon disposition of H.R. 2977, S. 1504 be returned to the calendar.

The **PRESIDING OFFICER.** Is there objection to the unanimous-consent request?

Mr. DOLE. No objection.

The **PRESIDING OFFICER.** Without objection, it is so ordered.

#### SAFE MEDICAL DEVICES ACT OF 1990

Mr. MITCHELL. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. 2783, a bill introduced earlier today by Senators KENNEDY and HATCH regarding the implementation of the Safe Medical Devices Act of 1990.

The **PRESIDING OFFICER.** The bill will be stated by title.

The assistant legislative clerk read as follows:

A bill (S. 2783) to amend the Federal Food, Drug, and Cosmetic Act with respect to medical devices and for other purposes.

The **PRESIDING OFFICER.** Is there objection to the request of the Senator from Maine?

There being no objection, the Senate proceeded to consider the bill.

Mr. KENNEDY. Mr. President, the Medical Device Amendments of 1992 represent several modifications that Senator HATCH and I have developed to facilitate better implementation of the Safe Medical Devices Act of 1990. These modifications have been developed in consultation with the administration, the affected industries, and consumer representatives. Senator HATCH and I have agreed to the following statement of explanation as to the legislative intent of the bill:

#### STATEMENT ON THE MEDICAL DEVICE AMENDMENTS OF 1992

Section 1. Short Title and Reference.  
Section 1 states that the short title is the "Medical Device Amendments of 1992."

Section 2. Effective Date and Regulations to Implement Section 519(e).

Section 2 pertains to the timetable for issuing final regulations and the effective date for final regulations for section 519(e) of the Federal Food, Drug and Cosmetic Act ("FFDC Act"). Section 519(e) was added by section 3(b) of the Safe Medical Devices Act of 1990, Pub. L. 101-629 ("SMDA"). The SMDA required the Food and Drug Administration ("FDA") to issue proposed regulations within nine months of the date of enactment (August 28, 1991), and final regulations nine months later (May 28, 1992). It also provides that if the agency misses the deadline for the final regulations, the proposed regulations will go into effect and become the final regulations, with the statute to take effect immediately.

The FDA issued the proposed regulations to implement section 519(e) on March 27, 1992. Even though the deadline for the final regulations is May 28, 1992, the agency provided a 60-day comment period. Thus the comment period will close one day before the final regulations are due to be issued. The agency has informed the Congress that it does not intend to issue the final regulations by the May 28 deadline.

Section 2 would extend the deadline to issue final regulations by 6 months, or until November 28, 1992. The agency has indicated that this extension will allow sufficient time to issue the final regulations. However, if the final regulations are not issued by November 28, 1992, then Section 2 provides that the proposed regulations will become the final regulations on November 29, 1992. The FDA is directed to publish promptly in the Federal Register notice of the new status of the proposed regulations.

Section 2 also provides that the final regulations will go into effect 9 months after they are published or no later than August 29, 1993 (9 months after November 29, 1992). This date may not be extended by the FDA under any circumstances.

In some cases, device manufacturers may need to obtain a section 510(k) clearance or an approval of a supplemental device application prior to initiating tracking of devices. This could occur where an effective tracking system required new packaging (such as single packaging instead of bulk packaging) or an alteration in processing (such as the sterilization of the product). It is expected that the FDA will expedite decisions on such clearance applications so that manufacturers can have tracking systems in place by the effective date of the regulations.

Section 3. Postmarket Surveillance.  
Section 3 makes failure to comply with a requirement imposed by section 522 of the FFDC Act (Postmarket Surveillance) a pro-

regulation that comes into effect when one side is hopelessly behind.

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