
21 U.S. Code § 360bbb-8c

Patient participation in medical product discussion

(a) Patient engagement in drugs and devices

(1) In general

The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

- (A) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and
- (B) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

(2) Protection of proprietary information

Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5 as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

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