



**Patient Safety Action Network**  
*Patient Driven, Patient Led*



## **PATIENT SAFETY ADVOCATES' RESPONSE TO HR 9733, CREATING A NATIONAL PATIENT SAFETY BOARD**

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Our nation is desperately in need of a solution to the unacceptable number of preventable medical errors and harms that kill and injure millions of Americans every year. HR 9733 proposes to create a National Patient Safety Board (NPSB) focused on this problem. Ideally, this new federal agency should operate similarly to the National Transportation Safety Board (NTSB), which has been so instrumental in making our aviation system safe. This bill is an important first step toward safer, more accountable health care. However, in reviewing the text of the bill, we have concerns that critical issues relating to transparency and accountability are lacking and some important issues are unclear. Our organizations have been active in the NPSB Coalition and we strongly recommend the following changes to this legislation.

**1. Public interest:** The NPSB should be a public agency created to serve patients and the public. We should be careful to prevent it from functioning as an arm of the health care industry. The NPSB's Health Safety Team should not be a public-private collaboration. While wide-ranging advice should always be welcome, no part of the agency's decision-making and oversight should be delegated to private health care entities whose business interests may not parallel the interests of the public.

**2. Transparency:** The NPSB is a public resource. The information it gathers should be redacted only for patient identifying information and should be open to the public, as is the case with many other government databases. Reports should include names of facilities and names of drugs/devices/products and their manufacturers that are involved in patient harm.

**3. Authority:** The NPSB should be able to access and hold data from any entity covered by this legislation. It is not clear from the legislation as written whether the NPSB can maintain a database of its own as opposed to simply accessing selected data for specific projects. A comprehensive historical database is essential to the agency's mission of detecting trends and patterns in patient safety events. To carry out the mission of examining patient safety threats, the agency must be granted authority to undertake studies of patient safety concerns whether invited into a facility or not. This is explicitly excluded in the current legislation.

**4. Patient Safety Reporting System:** Multiple studies document the accuracy and importance of patient and family reports of harm. We strongly support the bill's provision for a Patient Safety Reporting System through which patients, health care providers and others can report harm events to the NPSB. However, the legislation fails to articulate a plan to integrate these reports into NPSB analyses and studies. These reports of harm events should be available online (with patient identifying information redacted) for the public to view and download, similar to the FDA MedWatch/MAUDE databases.

**5. Board Members:** NPSB board members should be prohibited from financial relationships or other active relationships with medical facilities, drug and medical product manufacturers, or medical insurance companies. At least 50% of the board must have a history of working in the public interest with experience in patient safety. Board members should be full-time employees who are adequately paid so their full attention is focused on ending medical harm.

**6. Patient and Family Input:** All the NPSB's work should be infused with patient and family input. This includes having patient representatives as members of the various agency teams and in official advisory roles.

These are the issues that the NPSB needs to address in order to fulfill its mission. Non-transparent approaches to patient safety have failed to stem the tide of health care harm. This legislation needs to move beyond current non-transparent systems like Patient Safety Organizations (PSOs) and the aggregated reports commonly issued by other government agencies. We look forward to working with the sponsors and the coalition to make the proposed agency into a board that will truly lead to patient safety.

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