
Abramson, Brown & Dugan

A T T O R N E Y S

March 5, 2025

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House Health, Human Services, and Elderly Affairs Committee
Hon. Wayne MacDonald, Chair
Hon. Lisa Mazur, Vice Chair

**RE: HB 701-FN – Relative to a Patient’s Right to Try Certain Emergency
Health Care Treatment Options**

Honorable Chair, Vice Chair, and Members of the Committee:

I am a member of the New Hampshire Association for Justice (“NHAJ”), a resident of Weare, and a medical malpractice lawyer who has represented many patients harmed by negligent medical care, including care involving the negligent use of drugs, biologic products, and devices. I also currently have a family member involved in a clinical trial.

While I believe this bill to be very well-intentioned and I certainly think we should foster advances in medicine by encouraging clinical trials, we also need to make sure those clinical trials are highly regulated, and performed reasonably and responsibly, protecting the rights of the patients involved in the trials as much as the industries running the trials, which this bill neither encourages nor requires. Consequently, I write in opposition to the proposed language of HB 701-FN as proposed.

I oppose the language of this bill for three reasons. First, it provides immunity from suit for any patient harm even if the drug, biologic product, or device is prescribed to or used on a patient in a negligent or reckless manner, which is prohibited by federal law. Second, it significantly expands the scope of the current law in RSA ch. 126-Z by expanding its applicability from patients with a “Terminal Illness” as defined in RSA 126-Z:1, IV, to patients with any “Life Threatening Disease,” which creates a virtually unlimited scope. Finally, the provisions regarding “Telehealth prescreening” and “Remote signing” are probably not enforceable in New Hampshire since they pertain to treatment of patients who reside outside of the state, so that conduct would be subject to the laws of the state in which the patient receives the treatment. It also may well be preempted by federal regulations governing clinical trials.



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The proposed amendment to RSA 126-Z:3, creating a paragraph III, states:

III. Notwithstanding any provision of law to the contrary, a manufacturer of a drug, biologic, or device, a pharmacist, a health care facility, a health care provider, or a person or entity involved in the care of a patient using a drug, biologic, or device is immune from suit for any harm done to a patient resulting from the drug, biologic or device [under the circumstances listed in paragraphs (a)-(c)]; and

(d) The manufacturer, pharmacist, facility, provider, or other person or entity has not engaged in willful misconduct....

A similar immunity provision is proposed for the new sections, RSA 126-Z:6, III, providing immunity from patient harm caused by the proposed Telehealth Prescreening, and RSA 126-Z:7, III, providing immunity for harm caused by Remote Signing of informed consent documents.

Legal immunity, of any kind, granted to any actor, infringes on the constitutional rights of New Hampshire Citizens to have a remedy in the justice system when they are harmed. It is essentially a special dispensation and “stay out of court” card for the actors involved, giving them the power to act negligently or recklessly, without regard for public safety or health, because there is no fear of accountability for their actions. Immunities shield negligent and reckless conduct, and should be reserved for only very extraordinary circumstances. It allows actors to engage in improper and unsafe behavior, because they have protection from a civil action, regardless of how egregious their conduct may be. It is effectively a license for corporate and personal irresponsibility, discouraging the need to develop methods and products that will protect public health and safety.

In the situation of clinical trials, it allows entities and providers to effectively conduct human testing without regard to the cost to the patients involved and without regard to the safety of the methods or manner of that testing.

Federal regulations prohibit exculpatory language from being used in consents for clinical trials to protect the human subjects of their testing. See 21 C.F.R. §50.20. Specifically, no consent to a clinical trial can require the patient **“to waive or appear to waive any of the subject’s legal rights, or release[] or appear[] to release the investigator, the sponsor, the institution, or its agents from liability for negligence.” 21 C.F.R. §50.20.**

Consequently, these statutory immunity provisions are in direct conflict with federal regulations for clinical trials and would be preempted by the federal regulations should harm to the patient happen. While there are some limited exceptions to this provision for extraordinary circumstances, such as when death is so imminent there is not time to get informed consent and no other action will prevent immediate death from

occurring, these circumstances are few and far between, and they are already present in federal law, and there is no need to have these immunity provisions in this statute.

The second problem with these proposed statutory amendments is that they vastly expand the scope of the current law, which was established for patients with “Terminal Illness,” by expanding its applicability to patients with “Life-Threatening Disease,” which creates a virtually unlimited scope. Almost all cancers are “life-threatening diseases,” although many are treatable. Heart disease and diabetes are “life-threatening diseases,” but they are often manageable through lifestyle changes and medications. Alzheimer’s disease and dementia are “life-threatening diseases,” but can often be managed for many years. Mental illnesses, including addictions, can be “life-threatening diseases,” but are often treatable. None of these conditions, except at their very end stages, would ever fall within the definition of “Terminal Illness,” as defined in current law and the language of these proposed amendments would allow clinical trials on patients for virtually any medical condition, regardless of whether that condition is a “Terminal illness,” as defined in RSA 126-Z:1, IV. This is a very slippery slope, which the legislature should not traverse lightly.

Finally, the provisions regarding “Telehealth prescreening” and “Remote signing” are probably not enforceable in New Hampshire, since they apply to patients who are out of state. If an out of state patient is screened for and consents to a clinical trial being run in New Hampshire, they need to be personally seen and treated in New Hampshire. If an out of state patient is harmed by a clinical trial caused by medical care they receive in another state, they will be subject to the rights and remedies allowed in their state for their injuries. Just because the provider or organization running the trial is in New Hampshire, if the care is provided in the patient’s home state, New Hampshire law will not apply at all, and federal regulations prohibit requiring patients to waive their rights to suit if they are harmed by a negligently administered clinical trial. This statute would most likely be preempted by federal law and regulations.

Moreover, these provisions encourage irresponsible use of clinical trials. Clinical trials are highly regulated for a reason. The pre-screening process and informed consent process are often the most important parts of a clinical trial to ensure it is being performed on patients who are truly eligible for the trial. Without an in-person screening examination and informed consent process, it is impossible to truly determine if a patient is medically or psychologically eligible to participate. Many persons with life-threatening mental illnesses, brain injuries, dementia, or other ailments do not have the capacity to independently sign documents and may sign any form put in front of them. There are times when remote contact may be acceptable for clinical trials, such as during follow up interviews or routine check-ins, but the initial screening and consent process and the actual trial administration must be performed in person, usually with a witness or co-participant, to ensure it is performed reasonably and safely to protect the health, welfare, and rights of the patient subjected to the trial.

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In sum, while this bill is well-intentioned, it has significant flaws and should not be adopted as drafted. The immunity provisions should be stricken; but if they are not, they must, at a minimum, be limited to only the extraordinary circumstances allowed by federal regulation. To provide blanket immunity to anyone under any circumstance is an extreme step, which requires extensive and thoughtful consideration and detailed implementation of a framework to prevent unnecessary harm to innocent patients and to encourage safe, reasonable, and responsible use of clinical trials. Such a framework is not present in HB 701-FN, and its language is both overly broad and inadequate to sufficiently protect the interests of innocent patients who might be harmed by these trials and then precluded from fair and just compensation for that harm.

For each of these reasons, I oppose HB 701-FN as written and ask the committee to deem it "Inexpedient to Legislate."

Thank you for your kind consideration of my concerns. Should you have any questions, please feel free to contact me.

Very truly yours,

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