

Testimony on Behalf of the New England Biotechnology Association (NEBA) and

Connecticut United for Research Excellence, Inc. (CURE)

In support of HB6610—An Act Concerning Vaccines

March 23, 2011

This testimony is to supplement the New England Biotechnology Association (NEBA) and Connecticut United for Research Excellence, Inc. (CURE) remarks regarding HB6610 made at the March 23, 2011, Public Health Committee hearing.

NEBA and CURE advocate on behalf of biomedical research and count among our members Connecticut's leading biotechnology companies and biomedical research institutions. Our overarching goal is to grow the biotech sector, create well paying and meaningful jobs and, of course, speed the progress towards new medical treatments and cures.

We are in support of HB6610 An Act Concerning Vaccines.

The issue of physician choice has increasingly been framed as a financial issue, necessary to save state dollars. In reality, it is a patient rights and public health issue.

We strongly believe that data, experience and law demonstrate that allowing healthcare providers to choose which vaccines to include in their clinical practice creates the potential for improving public health in Connecticut by several mechanisms: boosting immunization rates, protecting against more vaccine-preventable disease, preventing vaccine shortages, and better shepherding of resources.

We would ask the Committee to consider provider choice in the context of three questions:

1. First, what policy relating to the availability of Advisory Committee on Immunization Practices (ACIP)-recommended vaccines in Connecticut will deliver the best public health and highest immunization rates?
2. Second, what policy will deliver the most financial value, with the least administrative burden?
3. And finally, what do the Centers for Disease Control and Prevention (CDC) and national medical advisory groups recommend—and what does state and federal law require that you do around choice?

Regarding the first question around public health, it must be acknowledged that all vaccines in a therapeutic class are not interchangeable. Physicians are best positioned to decide which vaccines are most appropriate for each patient, and should have the authority to make that

decision based on clinical considerations. Formulation, dosing, clinical trial data, overall series selection and any special health concerns for that individual child may all play a role. Allowing healthcare providers to use sound medical judgment to choose the best vaccine for each individual patient ensures the highest quality patient care. Limiting provider choice unnecessarily restricts patient access to innovation and best practice. Further, in a time of extraordinarily high exemption rates and dramatic increases in vaccine hesitancy, the role of physician as trusted provider—including clinical decision making on vaccines—is more critical than ever.

It has been said that non-choice simplifies the immunization program for the physician leading to higher immunization rates, but the data does not support that argument. The vast majority of states offer provider choice. Only eight states in the country do not offer either full or partial provider choice like Connecticut and this “Non-Choice” style program does not lead to higher immunization rates as measured by the CDC. One half of the 8 states that currently employ this policy rank in the bottom half for immunization rates, 3 in the bottom 10 nationally and only one ranks in the top 5. The current trend is toward choice, with Washington, New Hampshire, Utah, Texas, Idaho and North Carolina all recently switching to allow providers to choose the vaccines for use in their clinical settings. If non-choice truly promoted high immunization rates, wouldn't this be represented by the majority of state policies? Choice policies support competition, innovation and stabilization of supply, guarding against vaccine supply shortages. Of the 16 ACIP-recommended vaccines for children 0-18 years of age, 5 are available from only one manufacturer and 7 from only two manufacturers. Without choice, 12 of the 16 vaccines are essentially sole-source, artificially and unnecessarily increasing risks around supply. A vaccine shortage in a choice state is not as universally disruptive as only some providers are at risk as the state negotiates for an alternative source. Vaccine manufacturing is a complex process that requires significant lead time—not days, but months or longer from manufacturing facility to physician. For example, it takes nearly a year to produce one batch of tetanus vaccine. Manufacturers are not usually in the position to immediately respond to a non-choice state needing back-up supply. Even with reallocation there can be serious consequences for on-time immunization—witnessed by the recent Hib vaccine shortage—as manufacturers struggled to revise production scheduling. Since 2000, vaccines that protect against 9 of the 16 vaccine-preventable diseases in children and adolescents have experienced significant supply shortages. This has required disruptive adaptations to immunization schedules to reduce the number of doses received and/or the prioritization of available vaccine to only high-risk groups.¹

Second question: what policy will deliver the most value and least administrative burden for the state? Some perceived cost-saving and administrative benefits afforded to the states under a

¹ Berndt et al. *“US Market for Vaccines: Characteristics, Case Studies, and Controversies”*2009.

non-choice system simply no longer apply. Non-choice policies were adopted to save state dollars and to simplify storage and distribution. Recent changes to the healthcare system by the passage of the Patient Protection and Affordable Care Act (ACA) and improvements to the national immunization program make these non-choice systems antiquated.

The Vaccines for Children (VFC) program was created as a Federal entitlement, with guaranteed annual appropriation for 100% of children who qualify based on state estimates and ACIP-recommended vaccines voted into the program. Section 317 and state funds have been used as a safety net to provide vaccines for children and adults who don't qualify for the VFC program. ACA regulatory changes make this stop-gap measure unnecessary. Insurance mandates for immunization coverage without cost-sharing means underinsurance for immunizations is a thing of the past.

In addition, the perceived savings afforded from non-choice are not actualized. A 2006 study of the Texas vaccine purchase policy, which only allowed providers to use the least expensive vaccine, found that total cost savings were a maximum of 1.5% of the entire Federal vaccine purchase in the state. Since that study, Texas has moved to full provider choice.²

Improvements to the national program support a full-choice policy and further minimize perceived benefits afforded by non-choice policies. For example:

- Beginning this past year, CDC adopted a contracting policy which allows manufacturers to adjust prices *downward* at any time during the year. Thus, non-choice decisions based on “best price” could be a short-term decision, as prices could change several times in one month. The minimal savings on state and Section 317 funding will be captured only if state has a choice policy in place.
- Storage and distribution have been simplified for the states. Departments of Health historically stored and distributed vaccines. Today orders are placed through the CDC and vaccines are shipped directly to doctors from federally-managed warehouses, eliminating the stock management challenges of storing and distributing multiple vaccines. States now manage and forecast a virtual supply, removing the risk of wastage. Soon doctors will order directly from the Federal warehouses, eliminating even coordination and input burden on the States.

Finally the question of national best practice recommendations and state and Federal law, the CDC and the National Vaccine Advisory Committee (NVAC) recommend choice as a strategy for improving access to vaccines in a variety of settings. Additionally, the VFC program and the ACA support choice. A goal of the VFC Program and accordingly the ACA, is to increase access to all ACIP recommended vaccines. Coverage of Preventive Service Regulations provisions require all group health plans and health insurance issuers to cover all immunizations for routine use in

² Morningside Research and Consulting, Inc. “Best Price or Best Value? Texas Vaccines for Children Purchasing Policies”. 12 September 2006. www.morningsideresearch.com

children, adolescents, and adults that “have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention”³ — without cost to the individual. This provision went into effect on 23 September 2010 and is expected to apply to all plans, as they lose their “grandfathered” status, within the next 18 to 24 months. ACIP makes recommendations for individual vaccines, not classes of vaccines.

The non-choice vaccine policy in the State of Connecticut has been in place for many years. A non-choice policy may have made sense a decade ago. That is no longer the case. Non-choice does not improve public health or raise immunization rates. It doesn’t save money or administrative hassle. It isn’t supported by ACA or NVAC.

We humbly ask the Committee to look beyond the anecdotes and consider the facts. What value is brought to the citizens of Connecticut by continuing with a non-choice policy? Choice is a public health and a patient rights issue. In the shadow of ACA, why would Connecticut want to artificially limit children’s access to vaccines which have been recommended for use and adopted into the VFC program?

Thank you.

³ Section 2713, The Patient Protection and Affordable Care Act of 2010.