

Testimony of Paul R. Pescatello, JD/PhD

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Before the Committee on Public Health
Connecticut General Assembly, March 1, 2010

Re.: Raised Bill No. 270

An Act Concerning the Establishment of a Regional Policy on the Prohibition of Certain Gifts from Pharmaceutical and Medical Device Manufacturing Companies to Health Care Providers

Good morning.

I'm Paul Pescatello.

I'm president of Connecticut United for Research Excellence—CURE.

CURE's mission is to educate the public and policy makers about the life sciences in Connecticut and to work to grow the bioscience cluster of research institutions and biopharma companies in Connecticut.

We work to accomplish this mission in many ways and on many fronts—our BioBus mobile lab for middle and high schoolers, our new ScienceQuest mobile lab for elementary school kids, our advocacy for stem cell research.

Since the early '90s we've worked with UConn, Yale, the State and the biopharma community to ensure that cutting edge basic research done in Connecticut is developed and brought to patients as new medicines by Connecticut entrepreneurs and by Connecticut companies.

As I just said, we do this for the new medicines and therapies. We also do it for the economic development.

All those kids we're teaching in our mobile labs—we want jobs and career opportunities for them, here in Connecticut.

For Connecticut job seekers, biopharma companies are one of the few sources left for satisfying career opportunities. Jobs with robust benefits and a long time horizon—the 21st century equivalent of the stable base of manufacturing jobs Connecticut once had.

Now, I was going to say that another reason biopharma jobs are so attractive is that they're not easily outsourced.

This is true, if you mean outsourced beyond US shores. The sophisticated research and development of biopharma and its complex manufacturing is not easily transferred offshore.

But it can move easily across state lines.

And this brings me to Raised Bill No. 270, An Act Concerning the Establishment of a Regional Policy on the Prohibition of Certain Gifts from Pharmaceutical and Medical Device Manufacturing Companies to Health Care Providers.

This bill is a bill in search of a problem.

The problems it purports to address—gifts by biopharma companies to doctors and other health care providers—have long ago been successfully addressed.

They are already regulated by several different bodies.

The Food and Drug Administration tightly regulates what sales representatives can say about their company's products.

The federal Medicaid “anti-kickback” law prohibits sales representatives from making payments to physicians in return for the purchase, prescribing, endorsement or recommendation of a product reimbursed under a federal or state health care program.

American Medical Association guidelines address doctors' proper conduct of relationships with sales representatives.

Most importantly, the Pharmaceutical Research and Manufacturers of America has promulgated a strict code of conduct for sales representatives. This code is very similar, though not identical to RB 270. It accomplishes substantially the same goal as RB 270. I am not aware of a Connecticut biopharma company, selling medicines, that does not adhere to the PhRMA code.

I would ask this Committee, who is clamoring for this legislation? Where's the public outcry?

There isn't a public outcry because there aren't any gift harms being perpetrated.

There are urban legends about lavish entertainment, but that's all they are—conjured up fictions.

Theater tickets? Banned.

Sporting events? Banned.

Leisure/vacation trips? Banned.

What's left? The PhRMA code, like Raised Bill 270, allows "modest, occasional meals."

Taking action against conjured-up bogymen would be OK if it was harmless. But it isn't.

Biopharma companies are companies, which is to say they are businesses.

I think all of us are aware just how deep the recession has been. Connecticut's biotech community has weathered the economic storm well, but it has not been immune.

Venture capital, which funds biotech R&D, remains on the sidelines, waiting for the economic climate to improve before making new commitments. Connecticut biotechs are stretching six month budgets into 18 and 24 month budgets. I'm not aware of a single CURE company that hasn't put off investment in new equipment or personnel, or asked employees to make some significant sacrifice, to keep their research projects on track.

And so the core question is, is there some harm being done by biopharma companies that looms so large and bad that Connecticut needs to layer its own regulatory scheme atop the regulatory frameworks that already exist?

Now, you might say that this bill isn't that onerous, that it's so similar to preexisting regulation, what's the harm in a little more regulation?

Think of the typical biotech. Twenty, 30, maybe 50 employees at most. It takes them almost 15 years and almost \$1.5 billion—billion—to bring one project from proof-of-concept to FDA approved drug.

Duplicative, unnecessary, regulation like raised bill 270 won't particularly hurt the Pfizer's of the world. Unnecessary though it may be, a big company will add the burden of discerning the subtle differences among the various federal and state regulatory schemes—and then coming up with compliance protocols—to their preexisting compliance staffs.

A biotech, though, may have to divert an employee from research and development to compliance just to make sure they're not snagged by some subtle difference among the various regulatory schemes.

In raised bill 270's 15 pages I count no less than 23 duties and actions it places on Connecticut biopharma companies. And it's filled with subtle legalese—I count no fewer than five "limited, but not limited to" clauses.

Diverting an employee from medical research to sales practice regulatory compliance would be a good thing if there was a significant harm needing regulation, but if there really isn't such a harm, if all it's really about is posturing, faux action against a conjured up bogymen, the effect of bills like raised bill 270 is to slow medical R&D and, ultimately, to slow the introduction of treatments and cures patients are clamoring for.

I speak to a lot of patient groups—for Parkinson's, Alzheimer's, MS, Lou Gehrig's Disease, Diabetes—and I have to say there is a lot more clamoring to increase the pace of medical innovation than there is about biopharma sales rep sales practices.

Patients, as well, want to encourage physician interaction with sales representatives. They understand that doctors often receive critical up-to-the-minute information about treatments and side effects through their interactions with sales representatives.

I'll close by observing that we've got a schizophrenic approach to the biopharma industry in this state. We want the industry's shiny new labs and office buildings, its jobs and taxes. But when the scientists who've worked doggedly and in earnest for a decade or more creating a new medicine reach the finish line, we say "we don't trust you." For this coveted and most regulated of industries, we're going to fine tune and add fines to how you share a sandwich with a doctor.

It is naïve to think this approach doesn't register negatively with companies as they make choices about where to invest and grow.

Raised bill 270 is duplicative, wholly unnecessary and, ultimately, hugely counter productive.