Testimony Submitted by BioNJ
NJ Proposed Rule NJAC 13:45J NJ Division of Consumer Affairs Rule Proposal Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers

New Jersey Division of Consumer Affairs, October 19, 2017

Thank you for the opportunity to testify today on the proposed regulations put forth in N.J.A.C. 13:45J. I am Debbie Hart and I serve as the President and CEO of BioNJ where we represent 400 companies, many of which are pre-commercial product biotech companies and others marketing only one innovative product.

There is no denying it. There is an opioid crisis in the US, and all who are trying to make a difference on that front – most notably our Governor - should be lauded. In fact, several of our Member companies are working closely with the Governor to do just that.

To that end, it is unclear how the proposal that we are considering here today, while well intentioned, will impact that. And in fact, it will have unintended consequences that may squelch the very innovation that has the potential to eliminate opioid addiction and other devastating diseases.

It will restrict access to drugs in clinical trials for Patients and may inadvertently raise the cost of healthcare and impact the New Jersey economy in ways that we can ill afford.

It has the potential to do irreparable harm to the biotech industry we are trying so desperately to grow and that McKinsey & Company highlighted in a recent report, Reseeding the Garden State, as one of three bright spots in our future economy…if it is nurtured.

Let me first provide a brief background. While New Jersey has long been a leader in life sciences and a major contributor to New Jersey’s economy, much of that historically was due to the global pharmaceutical companies that were founded here or who chose to site their operations here. Over the past decade, New Jersey's economy, as well as the US economy, and the nature of the industry itself have all been transformed. One result is the relocation of much of the pharmaceutical research that was conducted here and New Jersey jobs that accompanied that relocation.

This could have created a dire future for New Jersey, but fortunately, the biotechnology sector of the life sciences industry in New Jersey has maintained, in large part, New Jersey's life sciences sector and positive economic impact on our state’s economy. There are now over 400 biotechnology companies in New Jersey, up from fewer than 50 two decades ago.

The main task of the new gubernatorial administration taking office in January will be to grow New Jersey's economy. Fortunately, as McKinsey cited in its report, the biotechnology industry offers the potential for growth. It will require a commitment from both the State of New Jersey and from the industry.

We are ready to do our part, but if these proposed regulations are enacted, we believe that there will be drastic unforeseen consequences that will impact not only our companies and the tens of thousands of employees who depend upon these jobs, but also New Jersey's higher education institutions, our burgeoning clinical research industry, and most importantly, patients here in New Jersey and around the world whose access to clinical trials and to life giving drugs and therapies may be delayed and even denied.
Please consider this: Clinical trials depend upon researchers and physicians to design and conduct the trials, as well as patients to participate in those trials. New Jersey presents an ideal landscape for clinical trials: talented researchers and a heterogeneous population in a geographically compact area. New Jersey currently conducts about 6 percent of all clinical trials conducted in the US, yet even that small portion creates 3,750 jobs and brings $337 million to New Jersey’s economy. We need to grow this industry, not work against it.

These proposed regulations would have a chilling effect on clinical trials: the $10,000 annual physician fee limit would not begin to cover the work necessary to design and oversee a clinical trial. As a result, companies would be forced to leave New Jersey for other states, impacting the academic institutions and the physicians that conduct the trials, as well as New Jersey patients who participate in those trials. Many of these patients suffer from rare diseases. Their entire life is a challenge. A clinical trial close to home often makes the difference in participation for our patients. If there are no clinical trials here, they may choose to participate at even greater hardship or forego the trial altogether.

New Jersey academic institutions will also suffer from these unintended consequences. After decades of underfunding from the State, our colleges and universities are beginning to grow their research programs so that they are desired partners of our biotech and biopharmaceutical companies. The opportunities for these partnerships will be curtailed due to these regulations.

And these academic partnerships are an essential component of New Jersey’s efforts to retain the best of our high school graduates, so many of whom take advantage of the opportunities at competing universities across the country that New Jersey ranks 49th - next to last - in retaining one of our greatest assets. And in many cases, they are lost forever along with the contributions they might have made.

Finally, our smallest and most promising biotech companies that are advancing the innovation and conducting the trials that would now be restricted by these regulations would suffer the most. And in some cases may pick up and move their locations and their trials...not to mention those that will not come in the first place. Ultimately the greatest loss will be the lost innovation to the Patient and to the economy of New Jersey.

Pre-product companies still in the research and development stages or those with only one product in development will not locate or remain in New Jersey because they simply cannot risk their company on the uncertainty that these regulations would create. Our companies depend upon interaction with physicians for clinical research, just as physicians utilize the education that they receive from our companies. Without that interaction, important advances will not happen...not in New Jersey anyway.

BioNJ fully appreciates the need to combat the opioid crisis in our state, but these proposed regulations are not a solution to that problem.

If we are trying to stifle innovation, reduce patient access to clinical trials and build a reputation as a red tape and business unfriendly state, this is one way to go.

But if we are trying to end the opioid epidemic, grow patient access to innovative new drugs and clinical trials such as the ones that gave us more quality time with my Mom after a lung cancer diagnosis in November 2015...and to make a difference for New Jersey, this is not the way.
Like the Governor, and like you in the Department, we in the biotech and biopharmaceutical industry want to see an end to the opioid crisis. We want to be part of the solution and would be pleased to partner with you and all interested parties to do so. Working together on constructive policies and legislation, I have no doubt that we can successfully address the crisis in New Jersey and potentially become the role model for our nation. Thank you for the opportunity to testify today.