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MEMORANDUM

DATE: April 29, 2015

TO: Members of the Delaware State Senate
and House of Representatives

FROM: Ms. Daniese McMullin-Powell, Chairperson
State Council for Persons with Disabilities

RE: S.B. 38 ("Right to Try" Act)

The State Council for Persons with Disabilities (SCPD) has reviewed S.B. 38 which would allow a terminally ill individual to acquire an investigational drug, biological product, or device which has successfully completed Phase One of a clinical trial but not yet received FDA approval. There are several safeguards in the bill, including a determination of the patient's treating physician that the patient lacks comparable or satisfactory treatment options approved by the FDA (lines 19-21). Informed consent is comprehensively defined (lines 34-55). A parent may consent for a minor; a guardian may consent for a ward (lines 24-26). According to the attached February 13, 2015 article, similar "Right to Try" legislation has been introduced in 26 other states and enacted in Arizona, Colorado, Louisiana, Michigan, and Missouri.

There are a few potential adverse consequences to the bill. For example, query whether manufacturers of the investigational drugs, products, and devices will be motivated to "market" them at high cost to desperate individuals despite a lack of proven benefit. Since insurers are not required to cover the costs of investigational drugs, products, and devices, it may also result in greater access by the affluent to remedies in short supply (lines 47-48).

The articles also note that FDA approval is an extended process which can result in lack of access to promising drugs. Moreover, only a very small percentage of patients are eligible to participate in clinical trials. Finally, positive and negative results may facilitate the approval review process.

After balancing the potential pros and cons of the legislation, SCPD is endorsing the proposed legislation. The advantages of access by terminally ill patients to products which have

successfully passed Phase One of a clinical trial outweigh negative considerations.

Thank you for your consideration and please contact SCPD if you have any questions regarding our position on the proposed legislation.

cc: Mr. Brian Hartman, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

SB 38 right to try act 4-29-15

2-12-15 NJ



WILLIAM BRETZGER/THE NEWS JOURNAL

State Sen. Colin Bonini, Dover Republican, plans to introduce a "Right to Try" law.

Bonini: Allow trial meds

JEN RINI
THE NEWS JOURNAL

Terminally ill Delawareans will be able to use experimental drugs not fully approved by the U.S. Food and Drug Administration for treatment under a bill proposed by state Sen. Colin Bonini.

With the blessing of their physicians and the drug company, patients would be able to sample drugs, products or devices that have passed the first phase of FDA clinical trials, Bonini explained, but are still far from being marketed

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will not be able to have their licenses revoked based on their recommendation and prevents state interference in implementing the policy.

"There's immunity for all parties involved," Bonini said. The FDA has not taken a position on any state's "Right to Try" law, said Sandy Walsh, an FDA spokeswoman.

Walsh said the FDA has allowed more than 99 percent of the requests the agency received from fiscal years 2010-2014 to proceed. In 2014, the FDA received 1,882 applications and approved 1,873. But, as in the "Right to Try" law, the drug company ultimately needs to provide the drug.

"In some cases in which patients were unable to secure a drug, it was due to the company's refusal to provide the drug, not FDA's failure to allow the use of the drug to proceed under expanded access," she said in a statement.

"It is critical for the public to understand that the FDA is not a barrier to accessing experimental drugs or medical devices."

Bonini will unveil the bill officially Thursday at noon in the Senate Hearing Room at Legislative Hall.

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similar to how some states have by-passed federal regulations by legalizing marijuana.

"One of the things I can see it (the legislation) doing is providing a modicum of hope," says Sean Hebbel, program director for Cancer Support Community Delaware.

Hebbel said patients often know there is a drug out there that can potentially help them, but there are just so many hoops to jump through.

People will do anything for a sliver of hope, he said, but they are often stuck waiting for years as a drug goes through clinical trials. The anxiety can be debilitating.

"I think that can be kind of cruel to be waiting for that," Hebbel said.

Bonini said there are safeguards built into the legislation. For instance, drug manufacturers are not required to provide the experimental drug or equipment at a patient's request and the patient's insurance company does not have to foot the bill.

Patients must have written documentation that their physicians recommend the treatment for their specific illness and include a clause that states that the patient is liable for all expenses and treatment for any adverse side effects.

The proposal states that physicians

Treatment

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and sold to the public.

"I think it just makes sense. It is a terrible situation people are facing and if we can perhaps save a life or two I think it will be well worth it," the Dover Republican said.

Delaware is among one of the 21 states including New Jersey, poised to consider "Right to Try" legislation this year, according to the National Conference of State Legislatures. In 2014, five states, Arizona, Colorado, Louisiana, Michigan and Missouri, passed similar measures. Bonini worked with the Goldwater Institute, a right-wing advocacy group based in Arizona, on his bill.

The FDA has had an "expanded access" application process in place since 2009 to help patients and physicians gain access to such experimental drugs. And last week, it introduced new guidelines intended to simplify that process.

But Bonini said the FDA's process is "very lengthy and complicated." The proposed state law, as with the other proposals, effectively ignores the jurisdiction of the federal government,

DELAWARE STATE SENATE REPUBLICAN CAUCUS



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A Word To Our Constituents

Editor's Note: *The following message is from Senate Republican Leader Gary Simpson.*



Sen. Colin Bonini introduces his "Right to Try" legislation at a press conference Thursday in Legislative Hall.

Sen. Bonini Announces 'Right To Try' Legislation

Bill Would Enable Terminally Ill Patients To Access Life-saving Treatments

DOVER - Bipartisan legislation announced this week by Sen. Colin Bonini (R-Dover South) would allow terminally ill patients to access safe investigational medications that could save their lives, even if those medicines are years away from hitting the market.

More than 500,000 Americans die each year of cancer alone, and thousands more of other terminal illnesses. Currently it takes more than a decade and a billion dollars to bring life-saving treatments to market. While there are over 20,000 safe drugs currently winding their way through the Food and Drug Administration approval process, only 3 percent of the sickest patients are eligible for clinical trials.

This means that the vast majority of patients die knowing that there may be a drug in development that could help them, but they are not allowed to have it.

"Nothing's more fundamental than the right to save one's life," Sen. Bonini said at a press conference Thursday in Legislative Hall. "This bill is fairly simple, it basically says that if you are facing the horrible situation of terminal illness and there is a drug that has passed at least Phase 1 of the FDA approval process, on the advice of your physician, you can get access to

those potential life-saving drugs."

Currently the FDA has a process that allows people to ask permission to access investigational medicines, a process that takes hundreds of hours of paperwork and months to navigate. While many people ultimately receive FDA permission, there are dozens of documented cases of people dying while waiting on their approval.

The proposed legislation takes the federal government out of the equation, potentially shortening wait times from months to days.

"What this bill should do is create a fast lane, if you will, and expedite the possibility of folks getting these life-saving drugs," Sen. Bonini said. "The bottom line is with this legislation we have the potential, if we're fortunate enough to get this passed, to save some lives. Hopefully this will be something that folks on both sides of the aisle and the governor will get on board with."

The measure is co-prime sponsored by two Democrats, Andria Bennett (D-Dover East) in the House and Karen Peterson (D-Stanton) in the Senate. Sen. Peterson joined Sen. Bonini at the press conference.

"I think it's a great bill," Sen. Peterson said. "I think all of us probably know somebody who could have availed themselves of this opportunity given the chance, I personally know several people. I think it's commendable and I'm glad to be supporting it."

Added co-sponsor Sen. Dave Lawson (R-Marydel), who also spoke at the press conference: "We've got to attack this insidious disease of cancer. This at least allows folks to try it and move it forward. And even if it doesn't directly benefit them it gives data to improve those drugs. We've got to get a handle on cancer; Delaware is one of the top states for it. So I think this bill certainly leads the way."

Delaware becomes the 27th state this year to introduce the law. Last year five states adopted Right to Try laws with overwhelming bipartisan support: Arizona, Colorado, Louisiana, Michigan, Missouri.

The Right to Try Act requires patients to be supervised by their own doctors and applies only to drugs that have already been deemed safe by the Food and Drug Administration.

Republican Message

Let's Leave Seniors
Out Of The Equation

'Right to Try' bill offers hope to terminally ill

2-23-15
NJ



DELAWARE VOICE
COLIN BONINI

Mikaela and Keith Knapp were high-school sweethearts who should have been enjoying the bloom of young love and marriage. Instead, at the start of 2014, they were desperately fighting to

gain access to a promising new medicine that had the potential to save Mikaela from certain death.

In October 2013, Mikaela was diagnosed at age 24 with renal cell carcinoma, a deadly form of kidney cancer that migrated into her bones. She exhausted all approved treatments in just a matter of months – but nothing worked. The Knapps learned about a new medicine being developed by three companies, but under the archaic rules of the U.S. Food and Drug Administration, the companies could only provide the medicine to patients enrolled in a clinical trial. The FDA denied her entry to every trial because of the advanced stage of her cancer.

Two years into their marriage, Keith launched a social media campaign to convince the FDA to relax its rules enough to give Mikaela a fighting chance. He posted videos on YouTube, started Facebook and Twitter campaigns, and began online petitions that brought in more than 400,000 signatures.

It wasn't enough. The FDA didn't help. Mikaela died on April 24, 2014. Five months later, on September 4, the FDA gave final approval to the drug that could have saved her.

Mikaela's tragic story has been repeated too many times in the United States. Medical researchers who develop promising new treatments typically spend a decade and \$1 billion to maneuver through the FDA's approval process. While a promising medicine is under review, only 3 percent of all patients who could benefit ever gain access through a clinical trial.

The FDA does have a process that allows patients to seek permission to access investigational medicines. But this "Compassionate Use" process requires a massive amount of paperwork and hundreds of hours to navigate. There are dozens of documented

cases of people dying while waiting for approval.

But Americans shouldn't have to ask the government for permission to try to save their own lives. They should be able to work with their doctors directly to decide what potential treatments they are willing to try.

An effort to make sure sick and dying Americans have access to the medications that could save them is sweeping the country. Last year, five states passed "Right To Try" laws that give terminally ill patients access to medicines that have passed FDA safety tests but are not yet on pharmacy shelves. This year, 27 states, including Delaware, are considering Right To Try laws.

When I heard about Right To Try, I knew it was right for Delaware. That's why I am proud to sponsor this bipartisan bill alongside two Democrats, Karen Peterson in the Senate and Andria Bennett in the House.

All across the country, Right To Try laws are winning bipartisan support. State legislatures adopted the law with nearly unanimous votes in Colorado, Louisiana, Michigan, and Missouri. The Right To Try was also approved by voters in Arizona by a margin of almost 4-1.

Right To Try is also having an impact on Washington. Just a few weeks ago, in response to this national movement, the FDA announced plans to revise the paperwork that doctors must submit to request permission to treat a terminally ill patient with an investigational medicine. The FDA said its goal is reduce a doctor's time to apply from 100 hours to 45 minutes.

That's a great move in the right direction, but it's not enough. Even though the forms in the first step of the process will be shorter, patients will still be required to submit an application asking the federal government for permission to try to save their own lives.

We need to remove barriers that prevent doctors from providing the care they are trained to give. And that's exactly what Right To Try will do. People should have access to the medications that could save them with no exceptions and no permission slip required.

Sen. Colin Bonini represents the 16th District, Delaware.