



February 5, 2024

The Honorable Charles Schumer
 Majority Leader
 322 Hart Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Matt Fuentes

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Leader Schumer,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the

biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients' lives.

The United States plays the leading role in the drug discovery that is at the core of the world's success in making extraordinary progress in reducing mortality from lethal diseases, and alleviating pain and suffering from chronic conditions. This progress was accelerated, in large part, by the bipartisan Bayh-Dole Act framework that incentivized a complementary and collaborative relationship between the public and private sectors in the drug development pipeline. Before the Act, less than five percent of 28,000 patents owned by the federal government had been licensed.¹ In other words, innovation that could have benefitted patients sat on the shelf.

While we commend President Biden's goal to make prescription drugs more affordable for American patients, this proposal does not address the underlying cost drivers that result in high out-of-pocket burdens for patients. Dismantling intellectual property protections could, however, initiate a long-term degradation of the drug discovery and development ecosystem in the United States. We are concerned for the potential harm to our patients—and all patients – that could result.

This is not a theoretical concern: Similar well-intended policies have failed patients before. In 1990, the National Institutes of Health adopted a “reasonable pricing clause” for medicines commercialized with a federal patent.² By 1995, the Director rescinded the clause, stating that, *“the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public...Eliminating the clause will promote research that can enhance the health of the American people.”*³

Innovation impacts the daily reality of patients fighting disease. We have seen countless lives improved, lengthened, and saved by new breakthrough treatments, many of which have been brought to market through investment in federal biomedical research.

We urge you to protect the research and development environment unleashed by the Bayh-Dole Act that makes these outcomes possible by standing with patients and urging withdrawal of the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* proposal before it can erode the American intellectual property ecosystem and slow the development of new treatments.

Please do not hesitate to contact Marcia Horn, President and CEO of ICAN, International Cancer Advocacy Network, at marcia@askican.org or at (602) 513-9217 for additional information.

Thank you for your leadership, and for your time and consideration of this critical issue.

Respectfully Submitted,

ICAN, International Cancer Advocacy Network, *and*

AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

Alliance for Safe Biologic Medicines

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February 5, 2024

The Honorable Marsha Blackburn
 357 Dirksen Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Chris Kelly

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Blackburn,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Ted Budd
 304 Russell Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Andrew Smith

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Budd,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Chris Coons
 218 Russell Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Katie Pannell

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Coons,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Tim Kaine
 231 Russell Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Samantha Koehler

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Kaine,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Roger Marshall
 479A Russell Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Charlotte Pineda

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Marshall,

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February 5, 2024

The Honorable Jerry Moran
 521 Dirksen Senate Office Building
 United States Senate
 Washington DC 20510

Attn.: Christiana Reasor

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Senator Moran,

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The Honorable Patty Murray
 154 Russell Senate Office Building
 United States Senate
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Attn.: Ijeoma Egekeze

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The United States plays the leading role in the drug discovery that is at the core of the world’s success in making extraordinary progress in reducing mortality from lethal diseases, and alleviating pain and suffering from chronic conditions. This progress was accelerated, in large part, by the bipartisan Bayh-Dole Act framework that incentivized a complementary and collaborative relationship between the public and private sectors in the drug development pipeline. Before the Act, less than five percent of 28,000 patents owned by the federal government had been licensed.¹ In other words, innovation that could have benefitted patients sat on the shelf.

While we commend President Biden’s goal to make prescription drugs more affordable for American patients, this proposal does not address the underlying cost drivers that result in high out-of-pocket burdens for patients. Dismantling intellectual property protections could, however, initiate a long-term degradation of the drug discovery and development ecosystem in the United States. We are concerned for the potential harm to our patients—and all patients – that could result.

This is not a theoretical concern: Similar well-intended policies have failed patients before. In 1990, the National Institutes of Health adopted a “reasonable pricing clause” for medicines commercialized with a federal patent.² By 1995, the Director rescinded the clause, stating that, “*the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public...Eliminating the clause will promote research that can enhance the health of the American people.*”³

Innovation impacts the daily reality of patients fighting disease. We have seen countless lives improved, lengthened, and saved by new breakthrough treatments, many of which have been brought to market through investment in federal biomedical research.

We urge you to protect the research and development environment unleashed by the Bayh-Dole Act that makes these outcomes possible by standing with patients and urging withdrawal of the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* proposal before it can erode the American intellectual property ecosystem and slow the development of new treatments.

Please do not hesitate to contact Marcia Horn, President and CEO of ICAN, International Cancer Advocacy Network, at marcia@askican.org or at (602) 513-9217 for additional information.

Thank you for your leadership, and for your time and consideration of this critical issue.

Respectfully Submitted,

ICAN, International Cancer Advocacy Network, *and*

AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

Alliance for Safe Biologic Medicines

Arizona Blood Alliance

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February 5, 2024

The Honorable Hakeem Jeffries
 Minority Leader
 2433 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Alexander Urry

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Leader Jeffries,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Katherine Clark
 Minority Whip
 2368 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Laila Goharioon

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Minority Whip Clark,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Pete Aguilar
 Democratic Caucus Chair
 108 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Elise Sugarman

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Chair Aguilar,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Jake Auchincloss
 1524 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Jess Wysocky

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Auchincloss,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Jim Baird
 2303 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Josh Weber

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Baird,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Ami Bera
 172 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Harsh Patel

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Bera,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Mike Collins
 1223 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Kevin Petroccione

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Collins,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

The United States plays the leading role in the drug discovery that is at the core of the world’s success in making extraordinary progress in reducing mortality from lethal diseases, and alleviating pain and suffering from chronic conditions. This progress was accelerated, in large part, by the bipartisan Bayh-Dole Act framework that incentivized a complementary and collaborative relationship between the public and private sectors in the drug development pipeline. Before the Act, less than five percent of 28,000 patents owned by the federal government had been licensed.¹ In other words, innovation that could have benefitted patients sat on the shelf.

While we commend President Biden’s goal to make prescription drugs more affordable for American patients, this proposal does not address the underlying cost drivers that result in high out-of-pocket burdens for patients. Dismantling intellectual property protections could, however, initiate a long-term degradation of the drug discovery and development ecosystem in the United States. We are concerned for the potential harm to our patients—and all patients – that could result.

This is not a theoretical concern: Similar well-intended policies have failed patients before. In 1990, the National Institutes of Health adopted a “reasonable pricing clause” for medicines commercialized with a federal patent.² By 1995, the Director rescinded the clause, stating that, “*the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public...Eliminating the clause will promote research that can enhance the health of the American people.*”³

Innovation impacts the daily reality of patients fighting disease. We have seen countless lives improved, lengthened, and saved by new breakthrough treatments, many of which have been brought to market through investment in federal biomedical research.

We urge you to protect the research and development environment unleashed by the Bayh-Dole Act that makes these outcomes possible by standing with patients and urging withdrawal of the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* proposal before it can erode the American intellectual property ecosystem and slow the development of new treatments.

Please do not hesitate to contact Marcia Horn, President and CEO of ICAN, International Cancer Advocacy Network, at marcia@askican.org or at (602) 513-9217 for additional information.

Thank you for your leadership, and for your time and consideration of this critical issue.

Respectfully Submitted,

ICAN, International Cancer Advocacy Network, *and*

AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

Alliance for Safe Biologic Medicines

Arizona Blood Alliance

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February 5, 2024

The Honorable Lou Correa
 2301 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Elizabeth Barrie

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Correa,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Don Davis
 1123 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Jonathan Miller

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Davis,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Madeleine Dean
 150 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Colleen Carlos

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Dean,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Suzan DelBene
 2330 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Abe Friedman

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative DelBene,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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Thank you for your leadership, and for your time and consideration of this critical issue.

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February 5, 2024

The Honorable Darrell Issa
 2108 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Giulia DiGuglielmo

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Issa,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Glenn Ivey
 1529 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Annette Christie

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Ivey,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

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February 5, 2024

The Honorable Hank Johnson
 2240 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Jocilyn Gilbert

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Johnson,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

The United States plays the leading role in the drug discovery that is at the core of the world’s success in making extraordinary progress in reducing mortality from lethal diseases, and alleviating pain and suffering from chronic conditions. This progress was accelerated, in large part, by the bipartisan Bayh-Dole Act framework that incentivized a complementary and collaborative relationship between the public and private sectors in the drug development pipeline. Before the Act, less than five percent of 28,000 patents owned by the federal government had been licensed.¹ In other words, innovation that could have benefitted patients sat on the shelf.

While we commend President Biden’s goal to make prescription drugs more affordable for American patients, this proposal does not address the underlying cost drivers that result in high out-of-pocket burdens for patients. Dismantling intellectual property protections could, however, initiate a long-term degradation of the drug discovery and development ecosystem in the United States. We are concerned for the potential harm to our patients—and all patients – that could result.

This is not a theoretical concern: Similar well-intended policies have failed patients before. In 1990, the National Institutes of Health adopted a “reasonable pricing clause” for medicines commercialized with a federal patent.² By 1995, the Director rescinded the clause, stating that, “*the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public...Eliminating the clause will promote research that can enhance the health of the American people.*”³

Innovation impacts the daily reality of patients fighting disease. We have seen countless lives improved, lengthened, and saved by new breakthrough treatments, many of which have been brought to market through investment in federal biomedical research.

We urge you to protect the research and development environment unleashed by the Bayh-Dole Act that makes these outcomes possible by standing with patients and urging withdrawal of the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* proposal before it can erode the American intellectual property ecosystem and slow the development of new treatments.

Please do not hesitate to contact Marcia Horn, President and CEO of ICAN, International Cancer Advocacy Network, at marcia@askican.org or at (602) 513-9217 for additional information.

Thank you for your leadership, and for your time and consideration of this critical issue.

Respectfully Submitted,

ICAN, International Cancer Advocacy Network, *and*

AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

Alliance for Safe Biologic Medicines

Arizona Blood Alliance

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February 5, 2024

The Honorable Tom Kean
 251 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Christopher Hall

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Kean,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Ted Lieu
 2454 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Felix Wu

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Lieu,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Zoe Lofgren
 1401 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Arlet Abrahamian

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Lofgren,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

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February 5, 2024

The Honorable Kevin Mullin
 1404 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Kate Adams

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Mullin,

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February 5, 2024

The Honorable Jerry Nadler
 2132 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Alison Cohen

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Chair Nadler,

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February 5, 2024

The Honorable Joe Neguse
 2400 Rayburn House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Ryan Shuman

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Neguse,

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February 5, 2024

The Honorable Scott Peters
 1201 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Dillon Cooke

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Peters,

On behalf of the patients we represent who are fighting lethal diseases, rare diseases, and chronic conditions, the 34 groups below are writing to express our concern regarding the National Institute of Standards and Technology proposed guidance, *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The proposal seeks to expand the federal government’s authority to use the Bayh-Dole Act’s march-in rights provision to re-license patents based on price objections. While well-intended, this jeopardizes the essential purpose and success of the Bayh-Dole Act, and threatens the biopharmaceutical investment and future innovation that we rely on to improve, extend, and save patients’ lives.

The United States plays the leading role in the drug discovery that is at the core of the world’s success in making extraordinary progress in reducing mortality from lethal diseases, and alleviating pain and suffering from chronic conditions. This progress was accelerated, in large part, by the bipartisan Bayh-Dole Act framework that incentivized a complementary and collaborative relationship between the public and private sectors in the drug development pipeline. Before the Act, less than five percent of 28,000 patents owned by the federal government had been licensed.¹ In other words, innovation that could have benefitted patients sat on the shelf.

While we commend President Biden’s goal to make prescription drugs more affordable for American patients, this proposal does not address the underlying cost drivers that result in high out-of-pocket burdens for patients. Dismantling intellectual property protections could, however, initiate a long-term degradation of the drug discovery and development ecosystem in the United States. We are concerned for the potential harm to our patients—and all patients – that could result.

This is not a theoretical concern: Similar well-intended policies have failed patients before. In 1990, the National Institutes of Health adopted a “reasonable pricing clause” for medicines commercialized with a federal patent.² By 1995, the Director rescinded the clause, stating that, “*the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public...Eliminating the clause will promote research that can enhance the health of the American people.*”³

Innovation impacts the daily reality of patients fighting disease. We have seen countless lives improved, lengthened, and saved by new breakthrough treatments, many of which have been brought to market through investment in federal biomedical research.

We urge you to protect the research and development environment unleashed by the Bayh-Dole Act that makes these outcomes possible by standing with patients and urging withdrawal of the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* proposal before it can erode the American intellectual property ecosystem and slow the development of new treatments.

Please do not hesitate to contact Marcia Horn, President and CEO of ICAN, International Cancer Advocacy Network, at marcia@askican.org or at (602) 513-9217 for additional information.

Thank you for your leadership, and for your time and consideration of this critical issue.

Respectfully Submitted,

ICAN, International Cancer Advocacy Network, *and*

AiArthritis, International Foundation for Autoimmune & Autoinflammatory Arthritis

Alliance for Safe Biologic Medicines

Arizona Blood Alliance

¹ <https://www.gao.gov/assets/rced-98-126.pdf>

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Neuropathy Action Foundation
Nevada Chronic Care Collaborative
Patients Rising Now
PD-L1 Amplifieds
Rare Access Action Project
Texas Rare Alliance



February 5, 2024

The Honorable Deborah Ross
 1221 Longworth House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Katie Paulson

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Ross,

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February 5, 2024

The Honorable Franklin Scott
 249 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Gabrielle Fazekas

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Scott,

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February 5, 2024

The Honorable Eric Swalwell
 174 Cannon House Office Building
 United States House of Representatives
 Washington DC 20515

Attn.: Lucas Lam

RE: Protecting American Intellectual Property by Protecting the Bayh-Dole Act’s March-In Rights Provision

Dear Representative Swalwell,

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