

June 29, 2016

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Mr. Darling,

We write today to ask the National Academy of Sciences to take action to address problems with the balance, perspective and independence of the National Research Council's (NRC) Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System (PIN: DELS-BLS-15-16). The one-sidedness of the committee creates enormous potential to introduce bias into the NRC's very important work on advising federal regulators at the United States Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration on how to update agricultural biotechnology regulations.

The current committee does not include the diversity of expert perspectives that exist in the mainstream scientific discourse, where there is great disagreement about how to regulate and deploy the products of biotechnology. Missing from the NRC are the viewpoints of scientists who advocate the precautionary principle and representatives from civil society who can speak to social dimensions of biotechnology regulations. Likewise, though a focus of the NRC project is on agricultural biotechnology, no farmers or farmer groups were invited to participate on the committee. Many such experts were nominated, yet NRC selected none as committee members.

By contrast, NRC invited many scientists and experts who work on the development of biotechnology applications to be committee members. NRC notes that two members have financial conflicts of interest, but many others have undisclosed conflicts, industry ties, or professional histories promoting biotechnology development. The outsized presence of such perspectives is at odds with the Federal Advisory Committee Act (FACA), which requires the NRC to form "fairly balanced" committees of scientists where conflicts of interests are avoided or disclosed if deemed absolutely necessary.

The problems we highlight in this letter confirm a troubling trend of one-sidedness at the NRC that jeopardizes public trust in the scientific credibility of the NRC. We invite the NRC to review a sign-on letter it received in 2000 as well as an issue brief published by Food & Water Watch in May 2016 (attached), both of which echo the complaints found in this letter.<sup>1</sup>

The NRC must live up to its federal obligations under FACA as well as its obligation to the public, which looks to the NRC as a premier, independent scientific institution. We ask that the NRC fully disclose all conflicts of interest among committee members and expand committee membership to include a diversity of expert perspectives. This necessarily includes inviting numerous critics of industry products and practices to participate at the committee level.

## Background

In July 2015, the White House announced it was undertaking a review of the Coordinated Framework of Biotechnology which provides a roadmap for how agricultural biotechnology products are regulated in the United States. The White House announced that an “independent analysis” would be undertaken to help it chart a new course for the Coordinated Framework.

*The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policy making. Due to the rapid pace of change in this arena, an external analysis should be completed at least every five years.<sup>2</sup>*

The National Research Council’s work on this project meets the definition of a Federal Advisory Committee, which states that government agencies can only use scientific opinions from the National Academy of Science if they emanate from “fairly balanced” committees that are free of conflicts of interests—“unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable...”<sup>3</sup>

## Financial Conflicts of Interests

Many of the proposed committee members work on the development of biotechnology tools and products that, in order to be successfully commercialized, may be subject to federal regulation. This presents an obvious conflict of interest given that the goal of the NRC project is to provide guidance to federal regulators about how to regulate biotechnology products.

The National Academy of Sciences’ conflicts-of-interest policy is quite clear in defining a financial conflict of interest:

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*...In assessing potential conflicts of interest in connection with an individual's service on a committee of the institution used in the development of reports for sponsors, particular attention will be given to the following kinds of financial interests if they are relevant to the functions to be performed: employment relationships (including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, and serving as an expert witness in litigation); stocks, bonds, and other financial instruments and investments including partnerships; real estate investments; patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.<sup>4</sup>*

As noted, under FACA, the NRC is instructed to avoid conflicts of interests, or disclose them if unavoidable. However, many committee members have clear financial conflicts of interest (described below), only two of which were disclosed.<sup>5</sup> Notably, all of these conflicts of interest

concern biotechnology developers—not companies or industry groups critical of or opposed to industry products and practices.

-- Steven Bradbury runs a private consulting firm whose web site advertises assisting clients in “registering innovative pest management technologies, including nano-based and biotechnology products.”<sup>6</sup>

-- Richard Amasino has biotechnology patents,<sup>7</sup> has engaged in political advocacy to reduce regulations over GMO crops,<sup>8</sup> and is listed as a Monsanto collaborator by a non-profit group associated with the University of Wisconsin’s patent and licensing operations.<sup>9</sup>

-- Farren Isaacs is a biotechnology developer and promoter,<sup>10</sup> has recently taken research funding from biotechnology companies like Gen9 and Dupont,<sup>11</sup> and has a biotechnology patent.<sup>12</sup>

--Richard Murray currently collaborates on biotechnology development with Amgen and the U.S. military.<sup>13</sup>

--The NRC acknowledges that Jeffrey Wolt and Steven Evans have financial conflicts of interests through their financial relationships with companies involved in biotechnology.<sup>14</sup>

Beyond financial conflicts of interests, some committee members have worked to advocate the development of biotechnology products, which presents an ideological position that clearly must be balanced. Food & Water Watch previously submitted comments to the NRC noting that 9 of the 13 invited committee members work on the development or promotion of biotechnology, have industry ties, or have financial conflicts of interests.

One example is NRC committee member Richard Johnson who recently served (and may continue to serve) as the head of the United States Council for International Business committee on biotechnology, which “fosters better appreciation for biotechnology’s societal benefits; seeks to prevent non science-based barriers to trade in biotechnology products; and advocates sound science and risk management as basis of regulatory approaches.” USCIB’s members include Monsanto, Dow and Dupont.<sup>15</sup>

Johnson also runs a private consulting firm called GlobalHelix that apparently has no website. Whether he has corporate biotechnology clients or not is unknown, but if so, this could present a financial conflict of interest. Johnson is a “retired partner” at Arnold and Porter,<sup>16</sup> a law firm that advocates the interests of its corporate biotechnology clients like Monsanto.<sup>17</sup>

## **Missing Perspectives**

Regrettably, the NRC has formed a one-sided committee of scientists despite having received nominations of numerous scientists and experts who could provide balance and perspective. NRC also received notice of the 100 signatory groups to the “Principles for Oversight of Synthetic Biology,” a document that provides a detailed, thoughtful analysis about how to safeguard biotechnology development, which is clearly relevant to the NRC’s current project.

The NRC also received notice of the hundreds of scientists who have signed on to the European Network of Scientists for Social and Environmental Responsibility's statement asserting there is "no scientific consensus on GMO safety." Any of these scientists and advocacy groups could provide much-needed perspective to the NRC, yet none were invited.

## **Conclusion**

The NRC frequently trumpets its position as a premier scientific institution that provides policy makers and the public with objective, independent scientific advice. Yet, since 2000, the NRC's work on agricultural biotechnology has been dogged by conflict-of-interest concerns and allegations of bias, stemming in part from the one-sided committees NRC initiates.

We echo these concerns in this letter, noting the lack of balance, independence and perspective of the Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System. We ask the NRC to review its requirements under FACA and take immediate action to engage experts and scientists on the committee who can provide balance and perspective, including critics. We also ask the NRC to publicly disclose all financial conflicts of interests among committee members.

Please direct any correspondence to Tim Schwab, Senior Researcher at Food & Water Watch. He can be reached at [tschwab@fwwatch.org](mailto:tschwab@fwwatch.org).

Sincerely,

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<sup>1</sup> Collins, Ronald et al. Center for Science in the Public Interest. Letter to Dr. E. William Colglazier, Executive Officer of the National Academies. May 22, 2000; “Under the Influence: The National Research Council and GMOs.” Food & Water Watch. May 2016.

<sup>2</sup> Executive Office of the President of the United States. “Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.” July 2, 2015 at Section III.

<sup>3</sup> Federal Advisory Committee Act. 5 U.S.C. app. §15 (b)

<sup>4</sup> National Academy of Sciences. Policy on committee composition and balance and conflicts of interests for committees used in the development of reports. May 12, 2003 at Financial Interests

<sup>5</sup> National Academy of Sciences. “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.” Committee Membership Information. Available at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49773> and on file. Accessed March 29, 2016.

<sup>6</sup> Steven P. Bradbury & Associates. Client Services. Available at <http://www.spradbury.com/client-services/> and on file. Accessed March 29, 2016.

<sup>7</sup> Amasino, Richard et al. “Transgenic plants with altered senescence characteristics.” Patent Number 6,359,197.

March 19, 2002; Amasino, Richard et al. “Transgenic plants with altered senescence characteristics.” Patent Number 5,689,042. March 19, 2002.

<sup>8</sup> “Scientists oppose plan to expand biotech regulation.” *Southwest Farm Press*. July 28, 2011; Fedoroff, Nina et al. Letter to Lisa Jackson, Administrator of Environmental Protection Agency. July 5, 2011.

<sup>9</sup> Wisconsin Alumni Research Foundation. Wisconsin Discovery Portal Faculty Profile: Amasino, Richard. Available at <http://discoveryportal.org/faculty.aspx?id=1396> and on file at Food & Water Watch.

<sup>10</sup> Hathaway, Bill. “Research in the news: Yale researchers create better cellular factories to churn out novel biopolymers.” *YaleNews*. November 16, 2015; Berger, Andy. “Engineered safeguard keeps GMOs in check.” *Discover*. November 30, 2015.

<sup>11</sup> Pirman, Natasha et al. “A flexible codon in genomically recoded *Escherichia coli* permits programmable protein phosphorylation.” *Nature Communications*. September 9, 2015.

<sup>12</sup> Church, George M. et al. U.S. Patent 8,569,041. “Multiplex automated genome engineering.” October 29, 2013.

<sup>13</sup> Murray, Richard. California Institute of Technology home page. “Cell-free expression of membrane proteins with applications to drug discovery.” Available at [http://www.cds.caltech.edu/~murray/wiki/index.php/Cell-Free\\_Expression\\_of\\_Membrane\\_Proteins\\_with\\_Applications\\_to\\_Drug\\_Discovery](http://www.cds.caltech.edu/~murray/wiki/index.php/Cell-Free_Expression_of_Membrane_Proteins_with_Applications_to_Drug_Discovery) and on file. Accessed March 30,

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[http://www.cds.caltech.edu/~murray/wiki/index.php/Biomolecular\\_Circuits\\_for\\_Rapid\\_Detection\\_and\\_Response\\_to\\_Environmental\\_Events](http://www.cds.caltech.edu/~murray/wiki/index.php/Biomolecular_Circuits_for_Rapid_Detection_and_Response_to_Environmental_Events) and on file. Accessed March 30, 2016.

<sup>14</sup> National Academy of Sciences. “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.” Committee Membership Information. Available at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49773> and on file. Accessed March 29, 2016.

<sup>15</sup> United States Council for International Business. 2014-2015 Annual Report. At 18, 20.

<sup>16</sup> National Academy of Sciences. “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.” Committee Membership Information. Available at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49773> and on file. Accessed March 29, 2016.

<sup>17</sup> McConnell, William. “Four law firms back Monsanto, say Syngenta’s antitrust fears groundless.” *The Street*. June 25, 2015.