William & Mary Environmental Law and Policy Review

Volume 44 *44 (2019-2020)*
Issue 2

Article 5

February 2020

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David B. Fischer

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David B. Fischer, *The IARC Monographs Program and the Federal Advisory Committee Act--Never the Twain Shall Meet?*, 44 Wm. & Mary Envtl. L. & Pol'y Rev. 531 (2020),
https://scholarship.law.wm.edu/wmelpr/vol44/iss2/5

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# THE IARC MONOGRAPHS PROGRAM AND THE FEDERAL ADVISORY COMMITTEE ACT—NEVER THE TWAIN SHALL MEET?

DAVID B. FISCHER*

## INTRODUCTION

At the eighteenth World Health Assembly[1] meeting in Geneva in 1965, the International Agency for Research on Cancer ("IARC") was voted into being.[2] This significant achievement was spearheaded by the United States and a mere handful of other countries,[3] all of whom agreed to annual contributions of $150,000 and to serve on the Governing Council.[4] IARC has since grown to have twenty-seven participating states,[5] and

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* David B. Fischer, M.P.H., JD, currently serves as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). He received a BA in Biochemistry and Molecular Biology from Northwestern University, an M.P.H. from the University of North Carolina School of Public Health, and a JD, with honors, from the University of Maryland School of Law, where he focused on environmental law. Mr. Fischer is also a patent lawyer. The author thanks Galen Rende for his stellar research in the preparation of this Article. This work is not a product of the United States Government or the United States Environmental Protection Agency. The author is not doing this work in any governmental capacity. The views expressed are his own and do not necessarily represent those of the United States or the U.S. EPA.

[1] The World Health Assembly is the governing body of the World Health Organization ("WHO"). *See* Walter Davis, *IARC: 20 years old*, WORLD HEALTH, Mar. 1986, at 28.

[2] *Id.* IARC in turn is part of the much larger Geneva, Switzerland-based WHO.

[3] *Id.*

[4] *Id.* The founding states included the United States, France, Germany, Italy, Northern Ireland, and the United Kingdom. *Id.* IARC also included a Scientific Council and a Secretariat. *See* WORLD HEALTH ORG., OFFICIAL RECORDS OF THE WORLD HEALTH ORGANIZATION, EIGHTEENTH WORLD HEALTH ASSEMBLY GENEVA PART II, PLENARY MEETINGS, VERBATIM RECORDS, COMMITTEES MINUTES AND REPORTS, NO. 144, at 640 (May 4–21, 1965), http://apps.who.int/iris/bitstream/handle/10665/85781/Official_record144_eng.pdf?sequence=1&isAllowed=y [https://perma.cc/E3H7-KV9Q]; *see also* IARC, STATUTE, RULES AND REGULATIONS 7 (May 2014), http://governance.iarc.fr/ENG/Docs/Statute_2014.pdf [https://perma.cc/4TGR-69WC]. IARC is governed by a Governing Council, which is populated by representatives of each participating state and establishes IARC policy. Neil Pearce et al., *IARC Monographs: 40 Years of Evaluating Carcinogenic Hazards to Humans*, 123 ENVTL. HEALTH PERSPECTIVES 507, 511 (2015).

[5] *Membership*, IARC, https://www.iarc.fr/en/about/membership.php [https://perma.cc/N5PU-WZWM] (last visited Dec. 3, 2019). The current member states include the United States, France, Germany, Italy, Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, India, Iran, Ireland, Japan, Morocco, Norway, the Netherlands, Qatar, Republic

each of their assessed annual contributions vary depending in part on "national resources."[6] Although IARC is part of the World Health Organization ("WHO"), it was envisioned from its inception to have significant autonomy.[7]

The involvement of the U.S. federal government in IARC, beyond its inception, has been steadfast and indispensable, especially with regard to IARC's Monographs Program ("the Program"), established in 1971 to address the growing need for cancer classifications of chemicals and other agents.[8] For decades, the United States, primarily through the National Cancer Institute ("NCI"),[9] has provided the bulk of funding for the Program—tens of millions of dollars to date, a sum that continues to grow each year.[10]

Although it remains a relatively small part of the much larger IARC, the Monographs Program's diminutive size belies its global impact. Monographs, developed by so-called working groups, often generate worldwide media interest,[11] along with "confusion, controversy, and criticism,"[12]

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of Korea, Russian Federation, Spain, Sweden, Switzerland, United Kingdom, Hungary, and Turkey. *Id.*

[6] IARC, REPORT OF THE GOVERNING COUNCIL WORKING GROUP AMENDMENT OF METHOD OF ASSESSMENT, FIFTEENTH SESSION 1 (Apr. 29–30, 1976), https://www.iarc.fr/wp-content/uploads/2018/07/annexe2GC51_9.pdf [https://perma.cc/A8FT-WDU7]; *see Funding*, IARC, https://www.iarc.fr/about-iarc-funding-assessed-contributions/ [https://perma.cc/QG6Z-4PRG] (last visited Dec. 3, 2019). Member states are classified into one of five Groups; Member states in Group 1, which contains both the United States and Japan, pay the highest assessment, approximately $2M each year. The U.S. State Department is responsible for paying the annual assessment to IARC. *See* U.S. DEP'T OF STATE, CONGRESSIONAL BUDGET JUSTIFICATION: DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS, FY 2019 56 (2019), https://www.state.gov/documents/organization/277155.pdf [https://perma.cc/9RQP-7ZKC].

[7] *See* Davis, *supra* note 1, at 28 (noting that IARC was to be run by a separate Governing Council).

[8] *See id.* at 28–29. *See generally* NIH, NOTICE OF AWARD, GRANT NO. 2U01CA033193-34 (Sept. 10, 2015), https://eelegal.org/wp-content/uploads/2018/02/CA033193-34-redacted_Redacted.pdf [https://perma.cc/7QTB-EAKP] [hereinafter GRANT APPLICATION].

[9] The NCI is one of over two dozen institutes and centers that constitute the National Institutes of Health. *See List of NIH Institutes, Centers, and Offices*, NIH, https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices [https://perma.cc/NK7R-S72P] (last visited Dec. 3, 2019).

[10] *See* Pearce et al., *supra* note 4, at 509. *See generally* GRANT APPLICATION, *supra* note 8.

[11] *See* GRANT APPLICATION, *supra* note 8, at 80 ("For selected Monographs covering agents of broad concern or outstanding importance to public health, press conferences are organized. Press releases are distributed to more than 4000 key mainstream and scientific media outlets worldwide . . . .").

[12] Kai Kupferschmidt, *High-Profile Cancer Reviews Trigger Controversy*, 352 SCI. 1504, 1504 (2016).

as evidenced by the Program's 2015 decision to classify glyphosate—the most widely used herbicide in the world—as "probably carcinogenic" to humans.[13] This unprecedented decision ignited not only a global reexamination of glyphosate's safety, but also provided a potent new weapon to both champions and detractors of the Program.[14] After all, no other scientific body had ever deemed glyphosate a carcinogen.[15]

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[13] *Id.*

[14] In November 2015, just a few months after the IARC Monographs Program issued its monograph on glyphosate, the European Food Safety Authority ("EFSA") published its own assessment of glyphosate. But, unlike IARC, the "EFSA concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans . . . ." *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 13 EFSA J. 4302, 4302 (2015).

Shortly after the EFSA published its assessment, Dr. Chris Portier—who had served on the IARC glyphosate working group, while he was also a consultant with the Environmental Defense Fund—"banded together" with scores of other scientists in a letter to Vytenis Andriukaitis, Commissioner of Health & Food Safety for the European Commission, to discredit the EFSA report and to tout the credibility of the IARC Working Group's conclusion that glyphosate is a probable human carcinogen. Letter from Dr. Christopher J. Portier et al. to Vytenis Andriukaitis (Nov. 27, 2015), https://www.efsa.europa.eu/en/press/news/160113 [https://perma.cc/ZW85-9A8W] [hereinafter Portier et al. Letter] ("We reviewed these two differing decisions on the human carcinogenicity of glyphosate and conclude that the IARC WG decision is by far the more credible.").

In a January 2016 response to Portier et al., Bernhard Url, the EFSA's Executive Director, pointed to the different evidence and the different methodologies as playing a role in explaining the divergences between the IARC's and the EFSA's assessments of the carcinogenic potential of glyphosate. Letter from Bernhard Url to Christopher J. Portier (Jan. 13, 2016), https://www.efsa.europa.eu/en/press/news/160113 [https://perma.cc/B6BQ-9YGV]. Url also underscored the EFSA's open and transparent process. *Id.* Although the letter mentions a forthcoming meeting between EFSA and IARC to exchange views, the meeting was never held.

Christopher Wild, the former head of IARC, had his own quarrel with EFSA. In his missive to Url, Wild raised concerns with EFSA's "misrepresentations of the IARC Monographs on the EFSA website and in distributed materials." Letter from Christopher P. Wild to Bernhard Url (Feb. 5, 2016), https://www.efsa.europa.eu/en/press/news/160113 [https://perma.cc/4NBF-68HA]. Even in the wake of IARC's unprecedented glyphosate decision, Wild heralded the IARC Monographs Program "as an authoritative standard for cancer hazard assessment around the world," and that "[t]ransparency, openness and scientific independence are assured throughout the evaluation process." *Id.* In the February 5th letter, Wild demanded that Url correct what Wild believed were factual errors "on the EFSA website and in distributed materials" before a planned joint meeting could take place between the EFSA and IARC. *Id.* In a February 9th response to Wild, Url countered that the parties should meet first and only then would Url commit "to correct any factual mistakes about IARC on our website should these remain." Letter from Bernhard Url to Christopher J. Wild (Feb. 9, 2016), https://www.efsa.europa.eu/en/press/news/160113 [https://perma.cc/4NBF-68HA]. The parties were unable to bridge the divide and never met.

[15] *In Defense of Scientific Integrity: Examining the IARC Monograph Programme and*

Champions could wield the glyphosate cancer classification as a sword to thwart glyphosate's continued use, especially in the European Union.[16] For detractors, the glyphosate cancer classification served as a quintessential example of the Program's persistent deficiencies, some of which were showcased at a February 2018 House Science Committee hearing.[17] Although IARC touts the Program's transparency and openness, the

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*Glyphosate Review: Hearing Before the H. Comm. on Sci., Space, & Tech.*, 115th Cong. (Feb. 6, 2018) [hereinafter *Hearing*] (statement of Lamar Smith, Chairman, H. Comm. On Sci., Space & Tech.) ("The Monograph Programme is alone in its determination that glyphosate poses a cancer threat. Both the EPA and EFSA, a European regulatory agency, have reviewed glyphosate and determined that the chemical is unlikely to cause cancer."); *accord* Letter from Congressmen Lamar Smith, H.R. Comm. on Sci., Space & Tech. & Andy Biggs, H.R. Subcomm. on Env't, to Christopher J. Wild, IARC Director, at 2 (Nov. 1, 2017), http://governance.iarc.fr/ENG/Docs/CLSBiggs-IARC_01112017.pdf [https://perma.cc/N5NH-CS3U] [hereinafter Smith & Biggs Letter] (noting that IARC was "the only agency to characterize glyphosate as 'probably' a carcinogen"); *see also Hearing*, *supra* (testimony of Anna B. Lowit, EPA) ("IARC's conclusion is inconsistent with the international community, where the EPA's conclusion that glyphosate is 'not likely to be carcinogenic to humans,' is consistent with other countries and international organizations including: Australia (2013), Canada (2015), Japan (2016), New Zealand (2016), the European Food Safety Authority (EFSA) (2015), Germany (2014), the European Chemicals Agency and the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Meeting on Pesticide Residues (JMPR) (2016)."). *See generally Glyphosate: Some facts about Glyphosate*, EUROPA, https://ec.europa.eu/food/plant/pesticides/glyphosate_en [https://perma.cc/FAQ7-2B6T] (last visited Dec. 3, 2019). In light of previous governmental risk assessments of glyphosate, it is unclear why IARC opted to conduct a more narrowly focused hazard assessment on what is without question a well-studied chemical. *Hearing*, *supra* (testimony of Timothy Pastoor, PhD) [hereinafter Pastoor testimony] ("At best this is a duplication of effort and at worst is an opportunity to sow confusion in the public's mind.").

According to Robert E. Tarone, PhD, had the Working Group assessing glyphosate conducted a proper summary of the rodent studies it would not have concluded that rodent studies provide sufficient evidence that glyphosate was an animal carcinogen. *Id.* (comments of Robert E. Tarone, PhD, on the IARC classification of glyphosate as a probable human carcinogen).

[16] *See* Portier et al. Letter, *supra* note 14.

[17] *See generally Hearing*, *supra* note 15.

Despite the global controversy, Kurt Straif, who until recently was the Head of the IARC Monographs Program, confidently asserted, "I'm very happy with the way we do things at the moment. We are really at the head of the scientific community," and "[t]his is really the strongest possible process." Kate Kelland, *How the World Health Organization's cancer agency confuses consumers*, REUTERS (Apr. 18, 2016), https://www.reuters.com/article/us-health-who-iarc-special-report-idUSKCN0XF0RF [https://perma.cc/NBQ4-HW3A].

Any confusion allegedly created by the Program's cancer classifications rests with others—media and industry—not with IARC. *Id.* Much of the criticism, Straif says, is coming from "people who are directly or indirectly affiliated with stakeholders that are not happy with us . . . ." *See* Kupferschmidt, *supra* note 12, at 1505.

public at large is, for all intents and purposes, shut out from the working group deliberations.[18] Nearly fifty years earlier, Congress grappled with similar deficiencies in the manner in which federal advisory groups were established and managed, ultimately leading to the passage of the 1972 Federal Advisory Committee Act ("FACA"), which sets forth, *inter alia*, strictures that govern advisory committees "established or utilized by" federal agencies.[19]

The potential intersection between the IARC Monographs Program, its working groups, and FACA may not be readily apparent, but given the close, decades long relationship between the IARC and the NCI, it is reasonable to ask whether the working groups are in fact advisory committees "established or utilized by" the NCI.[20]

This Article explores that question, perhaps for the first time, ultimately answering it in the affirmative. Extending FACA's reach to the IARC working groups and the manner in which they render cancer classifications may help to quell at least some of the ongoing controversy surrounding the Program.[21]

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[18] *See* Kelland, *supra* note 17.

[19] Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972).

[20] *Id.*

[21] The controversy surrounding IARC's glyphosate cancer classification is certainly not the first time the Monographs Program has garnered criticisms. In a 1998 letter to Dr. Gro Harlem Brundtland, Director General of the World Health Organization (in which IARC is situated), Michael Jacobson, Executive Director of the Center for Science in the Public Interest, along with four other scientists, unabashedly accuse IARC of rigging the review of saccharin to exonerate it (the working group classified saccharin in Group 2B—possibly carcinogenic to humans—rather than a higher cancer classification of Group 2A or Group 1). Michael F. Jacobson et al., *Letter to Dr. Gro Harlem Brundtland, Director General WHO*, 8 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 279, 279–80 (2002). In their letter, the authors called upon the WHO to—(1) "demand that the IARC withdraw its report [on saccharin]," (2) "appoint a new director for the chemical evaluation process," and (3) "appoint a new and balanced committee of unquestioned integrity, and then reevaluate saccharin." *Id.* at 279.

Harsh criticisms of the IARC Monographs Program extended into the 2000s. During 2002 and 2003, for example, the International Journal of Occupational and Environmental Health published several articles from scientists highly critical of the IARC Monographs Program and industry's influence on the make-up of the working groups and their bias toward downgrading the cancer classification of previously reviewed agents.

In a 2002 article in the journal, James Huff, former head of the IARC Monographs Program, accused J. Rice, head of the IARC Monographs Program from 1996 to 2003, and Paul Kleihues, IARC Director from 1994 to 2003, of ushering in an "era of 'downgrading' chemicals in general, often using 'mechanistic cover-ups,' with many of those chemicals/agents being placed unceremoniously into the nebulous category of 'unclassifiable as to carcinogenicity' [Group 3]." James Huff, *IARC Monographs, Industry Influence, and Upgrading, Downgrading, and Under-grading Chemicals: A Personal Point of View*, 8 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 249, 250 (2002).

Part I provides an overview of the IARC Monographs Program and its ongoing relationship with the National Cancer Institute. Part II explores the impetus of FACA, and reviews key provisions. Part III discusses FACA jurisprudence, focusing on *Public Citizen v. U.S. Department of Justice*, the seminal FACA case, and its D.C. Circuit progeny. Part IV pulls the pieces together in arguing that FACA applies to the working groups of the IARC Monographs Program.

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Huff notes that, "[s]o far, there have been 12 chemicals/agents downgraded by IARC, and all relatively recently under the Rice/Kleihues regime . . . ." *Id.* at 253. Eleven of the twelve were downgraded from Group 2B (possibly carcinogenic to humans), to Group 3 (not classifiable as to its carcinogenicity to humans). *Id.* Atrazine, a popular herbicide, was one of the eleven downgraded to Group 3. According to Huff, this downgrading was encouraged by Rice and others "in the belief that the alleged mechanisms are rodent-specific and would not be operative in humans." *Id.* Huff, however, asserts that "[t]hese are clearly and simply unproven speculations, not yet validated experimentally." *Id.*

Huff also accuses J. Rice of under-grading many chemicals by assigning them to a cancer classification group not commensurate with their cancer hazard. Huff cites 1, 3-butadiene as "probably the prime example of the overt influence of industry on the *IARC Monographs* process. This chemical remains in Group 2A (probably carcinogenic) rather than being upgraded into Group 1 (human carcinogen) . . . ." *Id.* at 254–55. In sum, compared with the Tomatis tenure at IARC, which according to Huff "clearly show[ed] a more public health attitude," the "Rice years . . . show[ed] an overwhelming industry influence." *Id.* at 260.

Paul Kleihues, MD, who at that time was the IARC Director, staunchly defended the IARC Monographs Program, noting that "[c]onsultants to industry are not considered ineligible to serve on Working Groups provided that they are permitted to publish their findings without oversight or censorship of any kind from their industrial sponsor." Paul Kleihues, *Integrity of the Conduct of the IARC Monographs Program*, 9 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 78, 78 (2003).

Kleihues also weighed in on the issue of downgrading agents—"The claim that there has been a systematic tendency to downgrade evaluations simply does not stand up to objective examination." *Id.* at 79. In a follow-up letter to the editor of the journal, Tomatis is decidedly unpersuaded—"In spite of the claim made by Professor Kleihues in his letter, doubts unfortunately remain about the influence that interests other than those of scientific truth and of public health may have had on evaluations of the carcinogenicity of certain agents . . . ." Lorenzo Tomatis, *The IARC Must Maintain Its Important Role in the Protection of Public Health*, 9 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 82, 82 (2003).

In a subsequent response to Kleihues's article, Huff reprises his condemnations—"Strangely, Kleihues/Rice remain adamant in refusing to admit or contemplate the truth of the criticisms leveled against the Monographs Program. Alleged conflicts of interest and overt industry participation and influence on the IARC Monographs must be addressed aggressively and independently." James Huff, *Industry Influences IARC Carcinogenesis Evaluations*, 9 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 82, 83–84 (2003); *see also* Jennifer Sass, *Continued Insensitivity to Conflicts of Interest at IARC*, 9 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 83, 83–84 (2003) ("The practice of allowing the regulated industries to freely participate in the discussions and decisions of the working groups compromises both public health and the scientific integrity of the Monographs.").

## I. THE IARC MONOGRAPHS PROGRAM

In 1970, IARC's Advisory Committee on Environmental Carcinogenesis recommended "that a compendium on carcinogenic chemicals be prepared by experts"[22] and that this compendium should reference and document "[t]he biological activity and evaluation of practical importance to public health . . . ."[23] The following year, the IARC Monographs Program was formally established under the stewardship of Lorenzo Tomatis.[24] The IARC's Governing Council, at its ninth session, subsequently ratified the importance and continuance of the Monographs Program by unanimously passing a resolution to continue "the preparation of monographs on the evaluation of carcinogenic risk of chemicals to man," after "considering that the Agency [(IARC)] should play an advisory role in the field of environmental carcinogenesis . . . ."[25]

The Monographs Program—as its name suggests—issues monographs, the instrument in which the IARC conveys and qualitatively evaluates the scientific information on the carcinogenicity of agents, which often include chemicals.[26] Each agent reviewed in a monograph is

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[22] IARC WORKING GROUP, IARC MONOGRAPHS ON THE EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO MAN VOLUME 1, at 8 (Dec. 1971). Prior to the Monographs Program, IARC initially envisioned creating two lists of chemical carcinogens—one for human carcinogens and another list for animal carcinogens—but this notion was soon abandoned for several reasons, including "the implicit danger that all chemicals not included in the 'black list' of carcinogens could be automatically assumed to be safe." Lorenzo Tomatis, *The IARC Program on the Evaluation of the Carcinogenic Risk of Chemicals to Man*, 271 ANNALS N.Y. ACAD. SCIENCES 396, 397 (1976). It is not at all clear, however, how the current list of carcinogens developed by the IARC Monographs Program avoids this "implicit danger." *Id.*

[23] *See* IARC WORKING GROUP, *supra* note 22, at 8.

[24] *See* Davis, *supra* note 1, at 29. Tomatis was the second director of IARC; his term extended from 1982 until 1993. RODOLFO SARACCI & CHRISTOPHER P. WILD, INTERNATIONAL AGENCY FOR RESEARCH ON CANCER: THE FIRST 50 YEARS (1965–2015) 143 (2015).

[25] IARC, HANDBOOK OF RESOLUTIONS OF THE GOVERNING COUNCIL OF THE INTERNATIONAL AGENCY FOR RESEARCH ON CANCER 14 (23d ed. 2018) [hereinafter HANDBOOK OF RESOLUTIONS].

[26] Monographs are issued in volumes; each volume may contain one or more monographs. *See* IARC, PREAMBLE TO THE IARC MONOGRAPHS 3 (Jan. 2019), https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf [https://perma.cc/LF7K-Y29T] [hereinafter PREAMBLE]. The Monographs Program initially focused on evaluating carcinogenic risks of chemicals to humans, but expanded its scope in 1987–1988 by dropping the words "of chemicals" in order to "denote the much-enlarged scope of the programme, covering physical, chemical, and biological agents as well as mixtures of compounds (like tobacco smoke) and circumstances" like some occupations. SARACCI & WILD, *supra* note 24, at 146–47.

In 2019, the Preamble to the IARC Monographs was updated, based in part on the comments submitted by numerous organizations, including the U.S. Department of

Health and Human Services (HHS) and the European Food Safety Authority (EFSA). *See, e.g.*, PREAMBLE, *supra*. Individual scientists and academicians also offered comments.

As discussed *infra* Part I, Monographs address the hazard of an agent under review, not its risk. Risk by definition involves a more comprehensive evaluation of an agent, taking into account hazard and exposure. Nonetheless, from its inception and for decades thereafter, the title of the Monographs had incorporated the term "risk" not "hazard." In its comments, HHS recommended a revised title: "IARC Monographs Evaluating Hazards related to Carcinogenic Risks in Humans." PUBLIC COMMENTS FORM: TO PROPOSE AN UPDATE TO THE PREAMBLE TO THE *IARC MONOGRAPHS* 150–51, https://monographs.iarc.fr/wp-content/uploads/2018/11/Preamble_PublicComments.pdf [https://perma.cc/6U3X-ZSNV] (last visited Dec. 3, 2019) [hereinafter PUBLIC COMMENTS TO THE PREAMBLE].

The EFSA offered a simpler change, replacing the word "risks" with "hazards" to yield: "IARC Monographs on the Evaluation of Carcinogenic Hazards to Humans." *Id.* at 121–22. IARC adopted the EFSA version. *See* PREAMBLE, *supra*, at 1.

HHS also suggested that IARC combine the Group 2A and Group 2B cancer classifications into a new Group 2 classification. HHS offered two alternative designations for Group 2: "Agent is suspect but further studies required," or "Partial evidence to be declared carcinogenic." PUBLIC COMMENTS TO THE PREAMBLE, *supra*, at 151. IARC rejected these suggested changes and instead retained both the longstanding Group 2A and Group 2B cancer classifications. *See* PREAMBLE, *supra*, at 1.

The National Cancer Institute (NCI) (which contributed comments to the HHS submission) recommended that "the preamble should describe a process for petition and redress of questionable decisions of prior monographs for the uncommon circumstance when new information casts doubt on a prior monograph or indicates reevaluation is warranted." PUBLIC COMMENTS TO THE PREAMBLE, *supra*, at 152. NCI expressed concern that without such a petition process the opportunity to consider new information might not occur until several years after it became available. *Id.* at 152–53. IARC rejected this suggestion. *See* PREAMBLE, *supra*, at 1. Although the revised Preamble now states "On occasion, IARC may select other agents if there is a need to rapidly evaluate an emerging carcinogenic hazard or an *urgent need to re-evaluate a previous classification*," IARC still selects agents to review "about every five years." *Id.* at 3 (emphasis added).

The Preamble also delineates three types of agents that the Monographs Program may review:

> (a) An agent not reviewed in a previous *Monograph*, if there is potential human exposure and there is evidence for assessing its carcinogenicity. A group of related agents (e.g., metal compounds) may be reviewed together if there is evidence for assessing carcinogenicity for one or more members of the group.
> (b) An agent reviewed in a previous *Monograph*, if there is new evidence of cancer in humans or in experimental animals, or mechanistic evidence to warrant re-evaluation of the classification. In the interests of efficiency, the literature searches may build on previous comprehensive searches.
> (c) An agent that has been established to be carcinogenic to humans and has been reviewed in a previous *Monograph*, if there is new evidence of cancer in humans that indicates new tumour sites where there might be a causal 8 association. In the interests of efficiency, the review may focus on these new tumour sites.

PREAMBLE, *supra*, at 3–4. Volume 1 of the Monographs was developed by an IARC Working Group, which was convened in Geneva from December 13–17, 1971. IARC WORKING

classified into one of four categories based on the scientific judgement of the working group: Group 1, the agent is carcinogenic to humans; Group 2A, the agent is probably carcinogenic to humans; Group 2B, the agent is possibly carcinogenic to humans; and Group 3, the agent is not classifiable as to its carcinogenicity to humans.[27] These formal IARC classifications were adopted in 1987–1988.[28] Prior to then, monographs expressed carcinogenicity "in a narrative style with variable language as suited to each Working Group."[29]

The Monographs Program assesses the hazard of agents, not their risks.[30] Hazard identification entails determining whether an agent is capable of causing cancer.[31] Whereas evaluating risk entails a more elaborate and informative process, which includes hazard identification as well as exposure and dose-response assessment to characterize the circumstances and probabilities by which the agent causes cancer.[32]

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GROUP, *supra* note 22, at 6. The monograph was finalized and made publicly available in 1972. SARACCI & WILD, *supra* note 24, at 145. The practice of convening working groups to develop monographs has continued to the present, although for many years meetings have been held in Lyon, France, where IARC is headquartered. *See* Pearce et al., *supra* note 4, at 509–10.

[27] PREAMBLE, *supra* note 26, at 35–36. The previous Group 4, "the agent is probably not carcinogenic to humans," was abandoned in the 2019 Preamble. IARC provided no explanation for this change. *See generally id.* (void of Group 4). *But see* SARACCI & WILD, *supra* note 24, at 145 (mentioning group 4).

[28] SARACCI & WILD, *supra* note 24, at 146.

[29] *Id.* at 145.

[30] PREAMBLE, *supra* note 26, at 1 (explaining that the previous title of the Preamble was changed from "the Identification of Carcinogenic Risks" to "the Identification of Carcinogenic Hazards," to be consistent "with the objective of the programme"). The terms "risk" and "hazard" are not interchangeable and the Preamble's new title should help avoid confusion surrounding these terms. *See id.* As noted in the Preamble, "[a] cancer hazard is an agent that is capable of causing cancer, whereas a cancer risk is an estimate of the probability that cancer will occur given some level of exposure to a cancer hazard." *Id.* at 2.

Occasionally the monographs will venture into the risk realm. For example, the monograph on red meat and processed meat consumption "concluded that each 50 gram portion of processed meat eaten daily increases the risk of colorectal cancer by 18%." Press Release, IARC, IARC Monographs evaluate consumption of red meat & processed meat (Oct. 26, 2015), https://www.iarc.fr/wp-content/uploads/2018/07/pr240_E.pdf [https://perma.cc/LK8T-P6QE].

[31] PREAMBLE, *supra* note 26, at 2.

[32] *See Conducting a Human Health Risk Assessment*, EPA, https://www.epa.gov/risk/conducting-human-health-risk-assessment [https://perma.cc/S826-YJDF] (last visited Dec. 3, 2019) (explaining the steps required to conduct a full risk evaluation); *see also* NAT'L RESEARCH COUNCIL, IMPROVING RISK COMMUNICATION, UNDERSTANDING HAZARDS AND RISKS 30 n.1 (1989) (explaining that one difference between hazard and risk is that risk "takes probability explicitly into account," while hazard does not). *IARC Monographs*

Consequently, under the IARC's cancer classification scheme, agents such as asbestos, tobacco smoking, and processed meat[33] are assigned the same cancer classification—Group 1, known human carcinogen—despite the fact that they pose vastly different risks.[34]

The work horses of the IARC Monographs Program are the working groups, assembled to consider the science on a particular agent under review and to render a cancer classification determination.[35] The objectives of each working group meeting are twofold—peer review and consensus, which does not necessarily mean unanimity.[36]

Generally, the IARC convenes three working groups each year to review agents.[37] A working group reviews one or more agents.[38] The IARC's working groups typically have members who have published on the agent under evaluation.[39] Some view this arrangement as injecting inherent bias into the review process.[40] As with other criticisms lodged at the IARC, Kurt Straif—former head of the IARC Monographs Program—brushed these concerns aside, claiming that the "IARC has a strong

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*Questions and Answers*, IARC, https://www.iarc.fr/en/media-centre/iarcnews/pdf/Monographs-Q&A.pdf [https://perma.cc/V6NP-FU27] (last visited Dec. 3, 2019). "The Monographs Programme may identify cancer hazards even when risks are very low with known patterns of use or exposure." As noted by Pastoor in his House testimony: "There are a wide variety of substances that may be labeled as carcinogenic . . . but in real life we could never consume enough or be exposed to enough to suffer adverse consequences." Pastoor Testimony, *supra* note 15, at 3; *see also* Alan R. Boobis et al., *Classification Schemes for Carcinogenicity Based on Hazard-Identification Have Become Outmoded and Serve Neither Science nor Society*, 82 REG. TOXICOLOGY & PHARMACOLOGY 158, 165 (2016) ("Chemicals with seven orders of magnitude difference in the dose required to cause cancer can be placed in the same category. This is how eating processed meat can fall into the same category as sulfur mustard gas.").

[33] WHO was quick to issue a clarification, stating, "[P]rocessed meat has been classified in the same category as causes of cancer such as tobacco smoking and asbestos (IARC Group 1, carcinogenic to humans), but this does NOT mean that they are all equally dangerous. The IARC classifications describe the strength of the scientific evidence about an agent being a cause of cancer, rather than assessing the level of risk." *Q&A on the carcinogenicity of the consumption of red meat and processed meat*, WORLD HEALTH ORG., http://www.who.int/features/qa/cancer-red-meat/en/ [https://perma.cc/QS8Z-DSN3] (last visited Dec. 3, 2019); *see also supra* note 15 and accompanying text.

[34] *See* WORLD HEALTH ORG., *supra* note 33.

[35] *See generally* GRANT APPLICATION, *supra* note 8.

[36] PREAMBLE, *supra* note 26, at 6–7, 11.

[37] Jack Siemiatycki et al., *Occupation*, *in* CANCER EPIDEMIOLOGY AND PREVENTION 324 (David Schottenfeld & Joseph F. Fraumeni, Jr. eds., 3d ed. 2006).

[38] *See* PREAMBLE, *supra* note 26, at 4.

[39] *See id.*

[40] Kelland, *supra* note 17.

belief . . . that those who know the most about certain exposures are those who have worked on such exposures."[41]

Meetings are held at the IARC in Lyon, France, and last for several days.[42] Four Subgroups, each responsible for a specific section of the monograph (i.e., "exposure data, cancer in humans, cancer in experimental animals, . . . and other relevant data"), peer review and revise draft documents that were prepared before the meeting by working group members with assistance from the IARC staff.[43] Each monograph concludes by classifying the agent as to its carcinogenicity.[44]

From its inception, and throughout its formative years and beyond, the IARC Monographs Program has turned to the NCI for assistance.[45] Indeed, the NCI's expertise and funding have sustained the IARC Monographs Program.[46] The Committee on Science, Space, and Technology calculated the total National Institutes of Health ("NIH") funding to the IARC from 1985 at over $48 million, of which over $22 million supported the IARC Monographs Program.[47]

The NCI's support, in fact, represents the lion's share of the IARC Monographs Program's budget.[48] This funding supports working groups

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[41] *Id.* In the application for NCI funding, Kurt Straif states unequivocally that "[t]he Monographs are unique in that they are developed by experts who conducted the original research." GRANT APPLICATION, *supra* note 8, at 76.

[42] *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, IARC (June 11, 2012), https://www.iarc.fr/media-centre-iarc-news-49/ [https://perma.cc/E5HA-A6EE]. The working group meetings can test the endurance of members—"We really worked around the clock, up late into the night and all weekend . . . ." Kelland, *supra* note 17.

[43] PREAMBLE, *supra* note 26, at 6.

[44] *Id.* at 22–23.

[45] The NCI assisted the IARC Monographs Program in assembling data on use and occurrence for the chemicals reviewed in Volume 1. Numerous Governing Council ("GC") Resolutions evidence the NCI's financial support to IARC and its Monographs Program including the following during the Program's formative years: In October 1972, the GC authorized the acceptance from NIH of up to $600,000 per annum for the programme. HANDBOOK OF RESOLUTIONS, *supra* note 25, at 186. In a May 1974 resolution the GC accepted NCI contribution "in amounts not to exceed U.S. $210,000 per annum." *Id.* GC authorized acceptance of NCI funds in amounts not to exceed $290,000 in April 1977. *Id.* at 189. In May 1978, the GC expressed "profound gratitude to the National Cancer Institute for . . . generous contributions to the work of the Agency." *Id.* at 190.

[46] Pearce et al., *supra* note 4, at 509. As noted by Tomatis himself, "[t]he NCI supports this program financially and has helped the Agency considerably by providing surveys of available pertinent literature." Tomatis, *supra* note 22, at 397.

[47] Smith & Biggs Letter, *supra* note 15, at 1.

[48] *See* Pearce et al., *supra* note 4, at 509 ("The IARC Monograph Programme is mainly funded by the U.S. National Cancer Institute . . . .").

to produce two of the three monograph volumes each year.[49] The NCI relies on a cooperative agreement as the funding mechanism, which, by its very nature, entails significant NCI programmatic involvement with the IARC Monographs Program "above and beyond the normal stewardship role in awards."[50] Fueled by NCI funding, the IARC Monographs Program churns out more cancer classification determinations[51] than any

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[49] *Department of Health and Human Services: Part 1. Overview Information*, NAT'L INSTS. HEALTH, https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html [https://perma.cc/R5C5-6BK3] (last visited Dec. 3, 2019) [hereinafter *Funding Announcement*]. The five-year commitment from the NCI is approximately $4.3 million. Email from Paulette Gray, Dir., Div. of Extramural Activities, Nat'l Cancer Inst., to Ron Johnson, Program Dir., DNA & Chromosome Aberrations Branch, Div. of Cancer Biology, Nat'l Cancer Inst. (May 20, 2014) (on file with author). Kurt Straif, former Head of the IARC Monographs Program initially requested nearly $5 million from the NCI. Kurt Straif letter to Ron Johnson, Program Dir., DNA & Chromosome Aberrations Branch, Div. of Cancer Biology, Nat'l Cancer Inst. (May 20, 2014) (on file with author). In FY 2017, the National Institute of Environmental Health Sciences, provided nearly $100,000 in supplemental funds to the IARC Monographs Program. *See Project Information: Evaluation of Carcinogenic Risks to Humans*, NAT'L INSTS. HEALTH, https://projectreporter.nih.gov/project_info_details.cfm?aid=9334069&icde=40932103 [https://perma.cc/QNF8-YGSQ] (last visited Dec. 3, 2019).

[50] *Funding Announcement*, *supra* note 49. NCI's involvement with the Monographs Program extends beyond financial support to encompass "substantial programmatic involvement required to 1) coordinate interactions between the NCI and the IARC Monographs program; 2) suggest agents to the IARC for evaluation; 3) identify resource individuals to attend or participate in Advisory or Working Groups of the IARC Monographs program; and 4) monitor performance and make recommendations for process improvements." Memorandum from Ron Johnson, Program Dir., DNA & Chromosome Aberrations Branch, Div. of Cancer Biology, Nat'l Cancer Inst., to Henry Khachaturian, Extramural Program Policy Officer, Office of Extramural Programs, NIH, Justification Memorandum for Use of Cooperative Agreement for RFA-CA-14-503, Limited Competition: International Agency for Research on Cancer (IARC) Monograph Program (U01) (Aug. 26, 2014) (on file with author).

The NCI's responsibilities include making recommendations to the IARC Monographs Program, and liaising between the Program "and other NCI and NIH programs to stimulate broader interactions, recommend agents for evaluation, identify resource individuals, disseminate results and leverage existing NIH resources and infrastructures." *Funding Announcement*, *supra* note 49.

[51] Since its inception in the early 1970s, IARC has evaluated over 1,000 agents. *See IARC Monographs*, IARC, https://monographs.iarc.fr/home/iarc-monographs-general-information/ [https://perma.cc/WVP6-FZB5] (last visited Dec. 3, 2019). Of these, 120 agents are in Group 1, carcinogenic to humans; 83 in Group 2A, probably carcinogenic to humans; 314 in Group 2B, possibly carcinogenic to humans; and 500 are in Group 3, not classifiable as to its carcinogenicity to humans. *See Agents Classified by the IARC Monographs, Volumes 1–125*, IARC, https://monographs.iarc.fr/agents-classified-by-the-iarc/ [https://perma.cc/E582-DEJG] (last updated Nov. 29, 2019). As noted previously, *supra* note 26, the Preamble has abandoned Group 4. Subsequently, IARC moved the one agent in Group 4—caprolactam—into Group 3. *See Agents Classified by the IARC Monographs, Volumes 1–124*, *supra* (moving caprolactam from Group 4 to Group 3 after Preamble update).

other agency, including for example, the U.S. National Toxicology Program's Report on Carcinogens[52] and the State of California's Proposition 65 Program.[53]

The IARC asserts that "[t]he Monographs conduct open and transparent evaluations . . . ."[54] Yet only a select few are permitted to attend IARC working group meetings, and no draft documents are ever released for public scrutiny and input.[55] Working group members and observers[56] attending the Monograph meetings must all sign a confidentiality agreement that requires them to, *inter alia*, "exercise the utmost discretion in all matters relating to the [Monographs] Advisory Process and not to communicate the deliberations and decisions of the Advisory Process to

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[52] "The Report on Carcinogens is a congressionally mandated, science-based, public health document that NTP prepares for the HHS Secretary. This cumulative report currently includes 248 listings of agents, substances, mixtures, and exposure circumstances that are known or reasonably anticipated to cause cancer in humans." *See 14th Report on Carcinogens*, NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T HEALTH & HUM. SERVS., https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html [https://perma.cc/G7PY-BZBC] (last updated Sept. 25, 2019).

[53] "Proposition 65 requires the state [of California] to maintain and update a list of chemicals known to the state to cause cancer or other reproductive toxicity." *See Proposition 65*, CAL. OFF. ENVTL. HEALTH HAZARD ASSESSMENT, https://oehha.ca.gov/proposition-65 [https://perma.cc/2XGQ-6XRV] (last visited Dec. 3, 2019); *see also The Proposition 65 List*, CAL. OFF. ENVTL. HEALTH HAZARD ASSESSMENT, https://oehha.ca.gov/proposition-65/proposition-65-list [https://perma.cc/BA93-KZTL] (last visited Dec. 3, 2019). The listing of chemicals, as of September 13, 2019, includes 623 carcinogens. *See* STATE OF CAL. ENVTL. PROT. AGENCY, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY, https://oehha.ca.gov/media/downloads/proposition-65//p65list091319.pdf [https://perma.cc/68BN-FEJS]. For a discussion of Proposition 65 and its infirmities, *see* David B. Fischer, *Proposition 65 Warnings at 30—Time for a Different Approach*, 11 J. BUS. & TECH. L. 131 (2016).

[54] GRANT APPLICATION, *supra* note 8, at 83.

[55] This pronounced lack of transparency was recently underscored by the House Science Committee—"Throughout the review process for the monograph, IARC, the only agency to characterize glyphosate as 'probably' a carcinogen, has kept drafts of its glyphosate report confidential. The other agencies that conducted review of glyphosate . . . were open about their processes, publishing information regarding public comments and draft reviews." Smith & Biggs Letter, *supra* note 15, at 2. The Congressmen requested that Wild provide the House Committee on Science, Space and Technology, "the names and contact information of IARC-affiliated individuals who would serve as potential witnesses for this hearing." *Id.* at 3. Wild responded to the letter but did not furnish the information requested. *See* Letter from Christopher J. Wild, Dir., IARC, to Congressmen Lamar Smith & Andy Biggs (Nov. 20, 2017), https://governance.iarc.fr/ENG/Docs/CPWild-LSmith&ABiggs.pdf [https://perma.cc/HF9N-T2YG].

[56] *See, e.g.*, *IARC Monographs—Volume 126—Request for Observer Status*, IARC (Mar. 27, 2019), https://monographs.iarc.fr/iarc-monographs-meetings/iarc-monographs-volume-126-request-for-observer-status/ [https://perma.cc/68PB-KNMZ].

third parties except as agreed by IARC/WHO."[57] In short, the procedures which govern working group meetings and the preparation of monographs stand in stark contrast to FACA requirements discussed *infra* Part II.

## II. THE FEDERAL ADVISORY COMMITTEE ACT—A BRIEF SYNOPSIS OF KEY PROVISIONS

The Federal Advisory Committee Act ("FACA") was passed in 1972 "to cure specific ills, above all the wasteful expenditure of public funds for worthless committee meetings and biased proposals . . . ."[58] and "reflects the good-government values that motivated its passage."[59] Until its passage, no federal legislation addressed the establishment and conduct of advisory committees, despite the plethora of committees relied upon by the federal government.[60] Literally thousands of advisory committees dotted the federal governmental landscape prior to FACA's passage, of which Congress was acutely aware.[61] "[T]he system of advisory committees that has grown up over the years might well be described as a fifth

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[57] *Confidentiality Undertaking*, IARC, https://monographs.iarc.fr/wp-content/uploads/2018/08/124-ConfidentialityUndertaking.pdf [https://perma.cc/7SZU-6HF8] (last visited Dec. 3, 2019).

[58] Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 441 (1989).

[59] Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 YALE J. REG. 451, 465 (1997). The General Services Administration ("GSA") administers FACA. Federal Advisory Committee Act of 1972 § 1, 5 U.S.C.A. App. 2 § 3(1) (West 1997). S. 3529, which amended H.R. 4383 to become the Federal Advisory Committee Act, was passed by both Houses and signed into law on October 6, 1972, and was itself an amalgam of "the best features" of three Senate bills—S. 1637, S. 1964 and S. 2064. S. REP. NO. 92-1098, at 4 (1972). For comprehensive information on FACA, guidance documents, and other pertinent information, see *Statutes and Related Legislation*, U.S. GEN. SERVS. ADMIN., https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/statutes-and-related-legislation [https://perma.cc/WQH5-4ZL5] (last updated Feb. 26, 2019).

[60] *Public Citizen*, 491 U.S. at 445–46.

[61] An exact count of federal advisory committees was unknown, but estimates were as high as 3,200. S. REP. NO. 92-1098, at 4. One agency listed 383 advisory committees, then revised the figure to 420, only to raise the count again to 511. H.R. REP. NO. 92-1017, at 3492 (1972). The vast number of federal advisory committees spawned concerns about their utility and the growing "belief that these committees do not adequately and fairly represent the public interest . . . ." S. REP. NO. 92-1098, at 5. Federal advisory committees often operated without adequate opportunity for public involvement. *Id.* at 6. Not all federal advisory committees of course were viewed with a jaundiced eye; many federal advisory committees provided useful and beneficial expert advice. *Id.* at 5. Congress's first attempt at inquiring into the operations of advisory committees was the 1070 Special Studies Subcommittee investigation. *See* H.R. REP. NO. 92-1017, at 3495.

arm of the Government, existing alongside the executive, legislative, judicial and regulatory arms."[62]

The growth and reliance on advisory committees was viewed by the public as indicia of governmental "inefficiency and indecisiveness."[63] In passing FACA, Congress wanted to reign in the power of special interests who "had too much influence over federal agency decision makers."[64] Through FACA, Congress explicitly declared that advisory committees should be established only when needed, terminated when no longer useful, and subject to governance standards and procedures.[65]

FACA section 3(2), defines an "advisory committee" as "any committee, board, . . . or other similar group, or any subcommittee or other subgroup thereof . . . which is (A) established by statute or reorganization plan, or (B) established or utilized by the President, or (C) established or

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[62] S. REP. NO. 92-1098, at 13.

[63] *Id.* at 5.

[64] U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-611T, FEDERAL ADVISORY COMMITTEE ACT: ISSUES RELATED TO THE INDEPENDENCE AND BALANCE OF ADVISORY COMMITTEES (2008). Hundreds of advisory committees dot the federal landscape. These advisory committees may take various forms, from boards to committees to councils, but if they dispense advice to a federal agency, they likely fall within the reach of FACA. The Environmental Protection Agency's Science Advisory Board, for example, "provide[s] independent advice and peer review to EPA's Administrator on the scientific and technical aspects of environmental issues." *See* EPA, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CHARTER (2017), https://yosemite.epa.gov/sab/sabproduct.nsf/Web/2017SABcharter/$File/SABCharter Sept2017.pdf [https://perma.cc/5KE9-3JSG].

On June 14, 2019, President Trump issued an Executive Order (EO) on Evaluating and Improving the Utility of Federal Advisory Committees. The EO, *inter alia*, mandates that each executive department and agency—with the exception of independent regulatory agencies—"evaluate the need for each of its current advisory committees." Exec. Order No. 13,875, 84 Fed. Reg. 28,711, 28,711 (June 14, 2019).

Under section 1 of the EO, each agency is required to "terminate at least one-third of its current committees established under section 9(a)(2) of FACA" unless a waiver is granted by the Office of Management and Budget. 84 Fed. Reg. at 28,711. A waiver may be granted "if the Director [of OMB] concludes it is necessary for the delivery of essential services, for effective program delivery, or because it is otherwise warranted by the public interest." *Id.*

Section 2 of the EO places limits on the creation of new advisory committees and imposes an overall cap of 350 on Government-wide advisory committees. *Id.* As with Section 1, waivers may be granted. *Id.* Section 3 delineates reporting requirements (e.g., "a recommendation for each of the agency's current advisory committees established by the President under section 9(a)(1) of FACA regarding whether the committee should be continued.") *Id.* at 28,712.

Sections 1–3 of the EO do not apply to an "advisory committee whose primary purpose is to provide scientific expertise to support agencies making decisions related to the safety or efficacy of products to be marketed to American consumers." *Id.*

[65] Federal Advisory Committee Act § 2(b).

utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government . . . ."[66]

Under FACA, no advisory committee can be established unless authorized by statute or by the President, or determined to be in the public interest by the head of an agency, after "timely notice published in the Federal Register."[67] Section 9 requires the filing of a charter before an

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[66] Federal Advisory Committee Act of 1972 § 1, 5 U.S.C.A. App. 2 § 3(2) (West 1997). S.3529 contained the words "established or organized," not "utilized." S. REP. NO. 92-1098, at 6 (1972). The terms established and organized were to be interpreted "in their most liberal sense," capturing within their reach "committees of the national academies where they are utilized and officially recognized as advisory to . . . an agency. . . ." *Id.* at 8. The conference substitute inserted the term "utilized" in place of "organized" without providing any explanation. H.R. REP. NO. 92-1403, at 3509 (1972) (Conf. Rep.).

Section 3(2) of FACA excludes from the advisory committee definition "(i) any committee that is composed wholly of full-time or permanent part-time, officers or employees of the Federal Government, and (ii) any committee that is created by the National Academy of Sciences [NAS] or the National Academy of Public Administration [NAP]." Federal Advisory Committee Act § 3(2). FACA was amended in the wake of and in response to the decision from the Court of Appeals for the District of Columbia in *Animal Legal Defense Fund v. Shalala*, discussed *infra* Part III, which held that FACA applied to advisory committees under the auspices of the NAS. 104 F.3d 424, 431 (D.C. Cir. 1997). Notwithstanding the court's rationale undergirding its holding, the Executive branch and both Houses of Congress all agreed that the NAS and NAP should not be subject to FACA's strictures. 143 CONG. REC. H10,578-02, 10,579 (1997). Even the plaintiffs in *Animal Legal Def. Fund* testified before Congress "that the full brunt of the Federal Advisory Committee Act should not apply to the academies." *Id.* at 10,579. Although H.R. 2977 amended FACA to exempt NAS committees from the definition of advisory committees, Congress also added a new section 15, which delineated requirements specifically applicable to the NAS and NAPA. Federal Advisory Committee Act § 15. Unlike Section 10's predilection to have all meetings, with few exceptions, open to the public, Section 15 takes a narrower view of public participation; only "meetings of the committee to gather data from individuals who are not officials, agents, or employees of the Academy are open to the public" (subject to FOIA disclosure exceptions). *Id.* § 15(b)(3). Similarly, the public's access to written documents is severely constrained—only final reports and "a brief summary of any committee meeting that is not a data gathering meeting" are available to the public. *Id.* § 15(b)(4). Through these amendments, Congress sought to "benefit the public and Federal agencies and . . . contribute to the quality and credibility of Academy reports." 143 CONG. REC. H10,578-02, at 10,580.

The White House Office of Management and Budget ("OMB") had wanted Congress to perform more radical surgery and entirely exclude from FACA "any committee created by an entity other than an agency or officer of the Federal Government and not subject to actual management and control by such agencies or officers." *Id.* at 10,579. Congress ultimately opted not to comport with the OMB's wishes. *Id.*

[67] Federal Advisory Committee Act § 9(a). This provision was aimed at stopping if not

advisory committee can "meet or take any action."[68] The contents of the charter include, among other pertinent information, the committee's objectives and scope; the length of time for the committee to complete its work and its termination date; and the committee's specific duties.[69] Advisory committees, as the name suggests, are to be used only for advisory functions, unless directed otherwise by statute or Presidential directive.[70]

FACA section 10 gives sweeping expression to Congress's desire to provide public participation and access to advisory committee proceedings.[71] Subject to limited exceptions, advisory committee meetings must be "timely" noticed in the Federal Register and open to the public; the public must be "permitted to attend, appear before, or file statements with any advisory committee"; and all documents—whether draft or final—must be made available to the public for inspection and copying.[72] Advisory committee meetings are held upon approval of a designated officer or employee of the federal government, who must also approve the agenda and attend the meeting.[73] Advisory committee membership must be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."[74]

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reversing "the trend toward bureaucratic proliferation of advisory committees." S. REP. NO. 92-1098, at 13.

[68] Federal Advisory Committee Act § 9.

[69] *Id.*

[70] *Id.* § 9(b).

[71] *See* Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 459 (1989) ("FACA's principal purpose was to enhance the public accountability of advisory committees . . . and to reduce wasteful expenditures on them.").

[72] Federal Advisory Committee Act § 10.

[73] *Id.*

[74] 41 C.F.R. § 102-3.30 (2018). GSA's final rule makes this obligation clear. FACA's language, however, assigns this obligation to the "President, agency heads, or other Federal officials" in establishing advisory committees, but only "[t]o the extent [it is] applicable." Federal Advisory Committee Act § 5. Neither the House nor Senate Report language discusses this phrase. H.R. REP. NO. 92-1017 (1972); S. REP. NO. 92-1098 (1972). Nonetheless, the House Report underscored the importance of a balanced committee membership as well as "assur[ing] that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment." H.R. REP. NO. 92-1017, at 3496; *see* Federal Advisory Committee Act § 5(b)(3). During hearings on FACA, testimony before the House Legal and Monetary Affairs Subcommittee "pointed out the danger of allowing special interest groups to exercise undue influence upon the Government through the dominance of advisory committees which deal with matters in which they have vested interests." H.R. REP. NO. 92-1017, at 3496; *see also* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 64 ("When the Congress enacted FACA in 1972, one

## III. *PUBLIC CITIZEN* AND ITS U.S. COURT OF APPEALS FOR THE D.C. CIRCUIT PROGENY

In 1989, nearly twenty years after Congress passed FACA, the U.S. Supreme Court confronted the contours and boundaries of FACA in the seminal case *Public Citizen v. U.S. Department of Justice*.[75] Public Citizen and Washington Legal Foundation brought suit against the Department of Justice ("DOJ") seeking a declaration that FACA covered the DOJ's utilization of the American Bar Association's ("ABA") Standing Committee on the Federal Judiciary.[76] The plaintiffs also sought an order requiring the DOJ to comply with FACA's requirements.[77] The DOJ, on behalf of the President, routinely seeks advice from the ABA Standing Committee on potential nominees for judgeships on the federal bench.[78]

As noted above, FACA applies to an advisory committee "established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies . . . ."[79] Because "Appellants agree[d] that the ABA Committee was not 'established' by the President or the Justice Department," the Court focused its spotlight on the term "utilized," "as Congress intended that term to be understood."[80]

Having recognized that "utilize" is "a woolly verb, its contours left undefined by the statute itself,"[81] the Court went in "search for other evidence of congressional intent to lend the term its proper scope."[82] The Court's quest swept through decades of both Executive branch and Congressional efforts to regulate the federal government's use of advisory committees.[83] Executive Order No. 11,007, signed by President Kennedy in 1962[84]—ten years before the passage of FACA—featured prominently

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of the principal concerns it was responding to was that certain special interests had too much influence over federal agency decision makers.").

[75] *Public Citizen*, 491 U.S. at 441.

[76] *Id.* at 440.

[77] *Id.*

[78] *Id.* at 443.

[79] Federal Advisory Committee Act § 3(2)(C).

[80] *Public Citizen*, 491 U.S. at 452. The Court also noted, "[e]qually plainly, the ABA Committee is a committee that furnishes 'advice or recommendations' to the President via the Justice Department." *Id.*

[81] *Id.*

[82] *Id.* at 454. The Court also was propelled in its quest by "the importance we have consistently attached to interpreting statutes to avoid deciding difficult constitutional questions where the text fairly admits of a less problematic construction." *Id.* at 455.

[83] *Id.* at 455–65.

[84] Exec. Order No. 11,007, 27 Fed. Reg. 1875 (1962). Executive Order No. 11,007 was signed by President Kennedy on February 26, 1962. *Id.*

in the Court's analysis, and was thought by the Court not only to be "the probable source of the term 'utilize' as later employed in FACA,"[85] but of wholesale provisions of FACA as well.[86]

In deciphering the word "utilized" the Court also canvassed FACA's legislative history. The Court noted, in particular, that the definition of "advisory committee" in FACA originated from the House definition of advisory committee but "with modification."[87] This modification referred to the addition of "or utilized" to "established" in the final legislation.[88] As remarked by the Court, "it appears that the House bill's initial restricted focus on advisory committees established by the Federal Government, in an expanded sense of the word 'established,' was retained rather than enlarged by the Conference Committee."[89] The Court went on to clarify that, "[t]he phrase 'or utilized' therefore appears to have been added simply to clarify that FACA applies to advisory committees established by the Federal Government in a generous sense of that term, encompassing groups formed indirectly by quasi-public organizations . . . 'for' public agencies as well as 'by' such agencies themselves."[90] The House Report too noted that "[t]he definition contained in H.R. 4383 includes advisory committees established by Congress or formed by the President as well as those formed by agencies of the Government."[91]

The Court readily acknowledged that FACA's "reach is extensive,"[92] but ultimately determined that the ABA Committee was not within "FACA's net," because the Committee was "an entity in receipt of no federal funds and not amenable to the strict management by agency officials . . . "; and was not "formed . . . by some semiprivate entity the Federal Government helped bring into being."[93] These determinants, although not laid down by the Court as explicit tests or criteria, nonetheless provide useful judicial field marks to assess FACA's reach.[94]

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[85] *Public Citizen*, 491 U.S. at 456.
[86] *See id.* at 455, 457 (noting that "like FACA, Executive Order No. 11007 stipulated that no advisory committee be formed or utilized unless authorized by law or determined as a matter of formal record by an agency head to be in the public interest . . . .").
[87] *Id.* at 457.
[88] *Id.* at 477.
[89] *Id.* at 462.
[90] *Id.*
[91] H.R. REP. NO. 92-1017, at 3494.
[92] *Public Citizen*, 491 U.S. at 453.
[93] *Id.* at 457–59, 463.
[94] Elsewhere in its opinion, the Court uses alternative language to describe groups that would fall within FACA's purview: groups that are "the offspring of some organization

The first application of the Supreme Court's teachings came in *Food Chemical News v. Young*, in the U.S. Court of Appeals for the D.C. Circuit, in which the court was asked to decide whether FACA applies to a panel of experts selected and managed by the Federation of American Societies for Experimental Biology ("FASEB") pursuant to FASEB's contract with the Food and Drug Administration ("FDA").[95] The court held that FACA did not apply to the panel of experts convened by FASEB.[96] In reaching its determination that the expert panel was established[97] by FASEB, not by the FDA, a federal agency, the court articulated indicia of a government-formed advisory group: "FASEB proposed the panel, and alone selected its members. FASEB also set the panel's agenda, scheduled its meetings, and would have reviewed the panel's work."[98]

The court also held that FASEB, not the FDA, "directly 'utilized' the panel."[99] The court reasoned that FASEB "is a private organization and government contractor; it does not have 'quasi-public status,'" and the panel, managed by FASEB, was "'not amenable to [any] management by FDA officials,' or 'by [any] semiprivate entity the Federal Government helped bring into being.'"[100]

In *Washington Legal Foundation v. U.S. Sentencing Commission*, the D.C. Circuit Court of Appeals grappled once again with the reach of FACA, this time determining whether an advisory group created by the

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created or permeated by the Federal Government," or "groups organized by, or closely tied to, the Federal Government, and thus enjoying quasi-public status." *Id.* at 461, 463.

[95] Food Chemical News v. Young, 900 F.2d 328, 329 (D.C. Cir. 1990).

[96] *Id.* at 333.

[97] *Id.* ("In the [Supreme] Court's delineation, as we understand it, 'established' indicates 'a Government-formed advisory committee,' . . . .").

[98] *Id.*; *see also* Byrd v. EPA, 174 F.3d 239, 247 (D.C. Cir. 1999) ("The record . . . belies any claim that EPA in fact 'established' the panel as required by FACA.") The court, however, might have reached a different result if EPA had exercised its veto authority in the panel selection process. For Judge Williams, in his dissent in *Byrd*, "[t]he veto power is key," whether or not it was exercised. *Id.* at 249.

*See* Judicial Watch, Inc. v. U.S. Dep't of Commerce, 736 F. Supp. 2d 24, 32 (D.D.C. 2010) ("[T]he government 'establishes' an advisory committee when the government directly forms it."); Wash. Toxics Coalition v. EPA, 357 F. Supp. 2d 1266, 1272 (W.D. Wash. 2004) ("A relationship between a federal entity and a developing committee does not, in itself, indicate that the government established that committee.").

[99] *Food Chemical News*, 900 F.2d at 333.

[100] *Id.* (quoting Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 463 (1989)). Drawing from FACA's legislative history, the Court's opinion also included the significant observation that FASEB is not an advisory committee subject to FACA because FACA "'does not apply to persons or organizations which have contractual relationships with Federal agencies.'" *Id.* at 331 (quoting H.R. REP. 92-1403, at 3509 (1972) (Conf. Rep.)).

U.S. Sentencing Commission was utilized by the DOJ.[101] "The dispute center[ed] around the quantum of control an agency must have over an advisory committee before it can be said to 'utilize' that committee."[102] Although the court acknowledged that DOJ would "exercise significant influence" on the commission's deliberations and its recommendations, it ultimately found that "influence is not control."[103] The DOJ's relationship with the advisory group was not "something along the lines of actual management or control."[104] In sum, the advisory group was not utilized by the DOJ as required by FACA.

In *Animal Legal Defense Fund v. Shalala*,[105] a committee assembled under the auspices of the National Academy of Sciences ("NAS")—the august body chartered by Congress during the American Civil War[106]—to revise the Guide for the Care and Use of Laboratory Animals.[107] The committee was funded through an NIH grant to NAS.[108] Applying the "management and control" test first articulated in *Public Citizen* and applied in both *Washington Legal Foundation* and *Food Chemical News*, the court readily concluded "that no government agency could be thought to exercise that degree of influence over the Guide Committee."[109] The appellants emphasized, however, that in *Public Citizen*, "advisory committees formed by the NAS were precisely the sort of advisory committees that would be covered by [FACA]."[110] The court agreed, reiterating part of the holding in *Public Citizen*, that "Congress had in mind an extension of the Act's coverage to include the offspring of 'quasi-public' organizations 'permeated by the Federal Government,'" which included NAS committees.[111]

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[101] Wash. Legal Found. v. U.S. Sentencing Comm'n, 17 F.3d 1446, 1448 (D.C. Cir. 1994).
[102] *Id.* at 1450.
[103] *Id.* at 1451.
[104] *Id.* at 1450.
[105] Animal Legal Def. Fund v. Shalala, 104 F.3d 424 (D.C. Cir. 1997). The NAS intervened as a co-defendant, joining HHS, the Public Health Service, and NIH. *Id.* at 426.
[106] *Who We Are*, NAT'L ACADS. SCI., ENGINEERING & MED., http://www.nationalacademies.org/about/whoweare/index.html [https://perma.cc/L4SV-F49T] (last visited Dec. 3, 2019).
[107] *Animal Legal Def. Fund*, 104 F.3d at 426.
[108] *Id.*
[109] *Id.* at 427; *see also* Byrd v. EPA, 174 F.3d 239, 247 (D.C. Cir. 1999) (rejecting appellant's assertion that the EPA utilized the benzene panel, even assuming arguendo that EPA exercised "much more control over" the benzene panel "than the agencies in *Food Chemical News* and *Washington Legal Foundation* exercised over the committees at issue in those cases").
[110] *Animal Legal Def. Fund*, 104 F.3d at 427.
[111] *Id.* at 429 (quoting Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 463 (1989)). The GSA, which administers FACA, promulgated a final rule on federal advisory committee management on July 19, 2001. *See* 41 C.F.R. § 102-3.30 (2018). The "final rule provides administrative and interpretive guidelines and management controls for Federal

Drawing from *Public Citizen*, the court in *Animal Legal Defense Fund* articulated two prongs of the "utilize test"—the first prong "is a stringent standard" and focuses on whether the federal agency manages or controls the advisory committee.[112] The second or alternative prong asks "whether an organization that establishes an advisory committee can be described as quasi-public."[113] In *Animal Legal Defense Fund*, the NAS committee failed the first prong but passed the second prong.[114]

## IV. FACA AND THE IARC MONOGRAPHS PROGRAM—"THE TWAIN" DO MEET

Since its very inception, IARC and its Monographs Program have been the beneficiaries of the U.S. government's largesse. Indeed, the NCI has been, and continues to be, the very life blood of the Monographs Program.[115] This ongoing interdependency, examined through the lens of *Public Citizen* and its progeny, prompts the question whether FACA applies to the working groups of the Monographs Program. If this question is affirmatively answered, then the Monographs Program working groups must be either "established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for . . . one or more agencies or officers of the Federal Government . . . ."[116]

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agencies to implement the provisions of the Act . . . ." Federal Advisory Committee Management, 66 Fed. Reg. 37,728 (July 19, 2001). According to GSA, "The proper statement of the 'utilized' test is whether an agency either has management of the committee *or*, in some fashion other than management, exercises control over the committee." *Id.* GSA cites only *Washington Legal Foundation* as "[t]he controlling legal authority," and inexplicably fails to cite *Animal Legal Defense Fund*, in which the court clarified its decision in *Washington Legal Foundation*. *Id.* at 37,729. The court in *Animal Legal Defense Fund* stated that in *Washington Legal Foundation*, "[w]e did not even refer to the alternative prong of the utilize test that comes from *Public Citizen*, i.e., whether an organization that establishes an advisory committee can be described as quasi-public." 104 F.3d at 430. The court continued, "[w]e quoted only the first prong drawn from *Food Chemical News v. Young*, 'so closely tied to an agency as to be amendable to strict management by agency officials.'" *Id.* (quoting Food Chemical News v. Young, 900 F.2d 328, 333 (D.C. Cir. 1990)).

[112] *Animal Legal Def. Fund*, 104 F.3d at 430.

[113] *Id. See* Judicial Watch v. U.S. Dep't of Commerce, 736 F. Supp. 2d 24, 32 (D.D.C. 2010) (drawing on the three aforementioned D.C. Circuit cases to articulate "three ways in which the government can 'establish' or 'utilize' an advisory committee so as to subject it to FACA obligations"). Although the court in *Judicial Watch* shies away from using the term "prong" it nonetheless accurately describes the two prongs described in *Animal Legal Defense Fund* in which an advisory committee is "utilized" and therefore subject to FACA requirements. *Id.* at 34.

[114] *Animal Legal Def. Fund*, 104 F.3d at 429–30.

[115] Pearce et al., *supra* note 4, at 509.

[116] Federal Advisory Committee Act § 3(2)(C). Both sections 3(2)(A) and (B) are

### *A. "in the interest of obtaining advice or recommendations"*

Under FACA section 3(2), an "advisory committee" must furnish "advice or recommendations for . . . one or more agencies . . . ."[117] There is ample evidence to demonstrate that the monographs produced by the IARC working groups satisfy this stricture. From their very inception, the monographs were to "be distributed to international and governmental agencies, . . . [made] available to industries and scientists . . . and . . . form the basis of advice from IARC on carcinogenesis from these substances."[118] Nearly forty years later, monographs continue to be "widely used and referenced by governments, organizations, and the public around the world."[119]

In the United States, "[t]he IARC Monographs . . . have been used extensively . . . to inform regulatory, legislative, and public health policy to protect Americans from exposure to potential cancer hazards."[120] The program "complements other U.S. efforts, often serving as a foundation for further evaluation or as the impetus for additional research."[121]

NCI cancer evaluations, budget documents, and other materials routinely reference and rely on IARC monographs cancer classifications.[122]

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inapplicable to the discussion *infra* Section IV.A on whether FACA applies to IARC Monographs working groups. Section 3(2)(A) addresses committees "established by statute or reorganization plan" and section 3(2)(B) addresses committees "established or utilized by the President." *See Judicial Watch*, 736 F. Supp. 2d at 32 ("The NACC [(North American Competitive Council)] is subject to FACA regulations if it was 'established' or is 'utilized' by the DOC [(Department of Commerce)].").

[117] Federal Advisory Committee Act § 3(2)(C).

[118] IARC WORKING GROUP, *supra* note 22, at 9.

[119] Pearce et al., *supra* note 4, at 508. Kurt Straif, the former Head of the Program, has stated that "[n]ational and international health agencies use the IARC Monographs as a trustworthy source of scientific information and as the scientific basis for their efforts to control cancer." *See* GRANT APPLICATION, *supra* note 8, at 6.

[120] *See Funding Announcement*, *supra* note 49.

[121] Email from William Robinson, Off. of Commc'ns & Pub. Liaison, Nat'l Cancer Inst., to Galen Rende (July 5, 2018) (on file with author). Similarly, the NCI has noted that the monographs "are considered critical references that inform health policy and cancer research worldwide about carcinogenic risks to reduce cancer burden globally." *Funding Announcement*, *supra* note 49; *see* Request for SPL/BSA Concept Approval, Requests for Applications (RFAs)/Contracts (RFPs), Limited Competition RFA for the IARC Monographs for the Evaluation of Carcinogenic Risks to Humans (May 1, 2014) (on file with author) (the IARC Monographs and their cancer "evaluations are significant both domestically for the NCI and other US health agencies as well as globally for health organizations worldwide.").

[122] For example, the 2002 IARC Monograph on smoking and cancer was highlighted in NCI's cancer research plan and budget proposal for FY 2005 as having "established a causal association between cigarette smoking and cancers . . . ." NAT'L CANCER INST., U.S. DEP'T HEALTH & HUM. SERVS., THE NATION'S INVESTMENT IN CANCER RESEARCH 38 (2005), https://www.cancer.gov/about-nci/budget/about-annual-plan/nci-plan-2005.pdf [https://

Similarly, "[i]n the Report on Carcinogens, a biannual report mandated by Congress and prepared by the National Toxicology Program at the NIEHS, the IARC Monographs are cited throughout their agent evaluations . . . ."[123]

### *B. "established or utilized by one or more agencies"*

As discussed in this section, in order for a federal agency to be said to have "established" an advisory committee, it must form the committee.[124] Applying this standard, working groups of the IARC Monographs Program are not "Government-formed advisory committee[s]";[125] they are instead created by the IARC Monographs Program staff.[126] The IARC staff select working group participants[127] and solicit nominees for working groups from the general public.[128] The NCI, as noted, can recommend members to serve on working groups, but the NCI does not have veto power over any of the members selected by IARC.[129] The FACA analysis does not end here, however. The two-prong "utilized by" test of FACA section 3 remains to be applied.

Although the ongoing cooperative agreement between the IARC Monographs Program and the NCI has been aptly described as a "partnership,"[130] this partnership does not rise to the level by which the NCI

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perma.cc/X92N-U9ZD]. IARC Monographs are also frequently cited in NCI's Tobacco Control Monograph Series. *See Tobacco Control Monograph Series*, NAT'L CANCER INST., https://cancercontrol.cancer.gov/brp/tcrb/monographs/ [https://perma.cc/WHC2-4MH4] (last visited Dec. 3, 2019). IARC Monographs are extensively cited as the basis for NCI's information on cancer-causing substances. *See Cancer-Causing Substances in the Environment*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/causes-prevention/risk/substances [https://perma.cc/8YM6-SQ2T] (last visited Dec. 3, 2019).

[123] *See* Email from Ron Johnson, Program Dir., DNA & Chromosome Aberrations Branch, Div. of Cancer Biology, Nat'l Cancer Inst., to Cherly Walker, Welch Chair & Director, Inst. of Biosciences & Tech., Texas A&M Health Sci. Ctr. (June 20, 2014) (on file with author). The email also touts how frequently the IARC website is visited: "The Monographs website is visited by people from approximately 125 countries and there are more than 150,000 distinct visitors each year. In 2013, an estimated 70,000 downloads of the List of Classifications (all agents evaluated by the program and their determined carcinogenicity) were made." *Id.*

[124] Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 458 (1989).

[125] Byrd vs. EPA, 174 F.3d 239, 246 (D.C. Cir. 1999) ("Byrd cannot show that [the benzene panel] was 'a Government formed advisory committee' as required by our narrow interpretation of 'established.'").

[126] PREAMBLE, *supra* note 26, at 5.

[127] *Id.*

[128] *See, e.g.*, *IARC Monographs—Volume 124—Call for Experts*, IARC (July 5, 2019), https://www.iarc.fr/wp-content/uploads/2019/07/QA_Monographs_Volume124.pdf [https://perma.cc/9FDF-ABHH].

[129] *See Byrd*, 174 F.3d at 249.

[130] GRANT APPLICATION, *supra* note 8, at 5 ("Under the cooperative agreement, the NIH

"exercise[s] actual management or control over"[131] the working groups, or that these groups are "amenable to [any] strict management by [NCI] officials."[132] Throughout the cancer classification process, the management of the working groups remains in the hands of the working group itself.[133] The grant application also makes clear that although the relationship between the NCI and IARC should be viewed as a "partnership," the NCI "is not to assume direction, prime responsibility, or a dominant role in the activities."[134] As with the NIH in *Animal Legal Defense Fund*, the NCI falls short of satisfying the stringent standard required in the first prong of the "utilized by" analysis.[135] The second prong offers the only remaining means by which FACA can be said to apply to working groups of the IARC Monographs Program.

The Court's sweep of legislative history in *Public Citizen* led it to conclude that the phrase "or utilized" expanded the reach of FACA to apply to advisory committees spawned by an organization considered "quasi-public" or "semiprivate" because it was created or permeated by the Federal Government.[136] In *Animal Legal Defense Fund*, the quintessential example of such a quasi-public organization was the National Academy of Sciences, "created by Congress to answer the government's request for investigations . . . and the government takes care of the expenses associated with performing these tasks."[137]

Similarly, the U.S. government played a key role in bringing the IARC into being, which it continues to fund through multiple federal funding streams, and in fostering and funding its Monographs Program since its inception.[138] Indeed, Tomatis has noted that, as a result of the NCI's financial support, the Monographs Program "has since been able to maintain an almost constant output of three volumes of monographs per year."[139]

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purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role . . . .").

[131] Judicial Watch v. U.S. Dep't of Commerce, 736 F. Supp. 2d 24, 32 (D.D.C. 2010).

[132] Food Chemical News v. Young, 900 F.2d 328, 333 (D.C. Cir. 1990).

[133] *See* GRANT APPLICATION, *supra* note 8, at 5.

[134] *Id.*

[135] Even if NCI's role mirrors that of the U.S. Department of Justice in *Washington Legal Foundation*, in which DOJ exercised significant influence over the advisory committee, the Court nonetheless held that "influence is not control." Wash. Legal Found. v. U.S. Sentencing Comm'n, 17 F.3d 1446, 1451 (D.C. Cir. 1994).

[136] Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 462 (1989); *see* Animal Legal Def. Fund v. Shalala, 104 F.3d 424, 429 (D.C. Cir. 1997).

[137] *Animal Legal Def. Fund*, 104 F.3d at 429.

[138] *See* Pearce et al., *supra* note 4, at 509.

[139] "[W]ith the generous financial support of the National Cancer Institute, the

And that the "partnership" relationship, which is part and parcel of the ongoing cooperative agreement, by definition necessarily "closely tie[s]" IARC and its Monographs Program with the NCI.[140] IARC, therefore, should be characterized as a quasi-public organization, satisfying the second prong of the "utilized by" analysis.

The cooperative agreement between the NCI and the IARC's Monographs Program expires in 2020.[141] Given the NCI's unbroken decades of support,[142] another five-year cooperative agreement is likely in the making. The cooperative agreement provides an effective vehicle in which to include an explicit provision subjecting the IARC Monograph working groups to FACA requirements.[143]

## CONCLUSION

In 1972, growing concerns about the conduct and sheer number of federal advisory committees culminated in the passage of FACA.[144] Chief among these concerns was the inaccessibility of committees to public participation and scrutiny.[145] Advisory committee proceedings were "unnecessarily closed to the public."[146] FACA's section 10 was designed to address this by "establish[ing] the standard of openness in advisory committee deliberations, and provid[ing] an opportunity for interested parties to present their views . . . ."[147] Openness was to be "liberally construed."[148]

The decades old clarion cry for advisory committees to operate in the full view of the public with limited exceptions applies equally well to the working groups of the IARC Monographs Program.[149] Although FACA was not intended to cover every conceivable advisory committee rendering advice to a federal agency, its reach extends to advisory groups of quasi-public

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program . . . has . . . been able to maintain an almost constant output of three volumes of monographs per year." Lorenzo Tomatis, *The IARC Monographs Program: Changing Attitudes towards Public Health*, 8 INT'L J. OCCUPATIONAL & ENVTL. HEALTH 144, 144 (2002).

[140] *See* GRANT APPLICATION, *supra* note 8, at 5.

[141] *Id.* at 1.

[142] *See* Pearce et al., *supra* note 4, at 509.

[143] *See* GRANT APPLICATION, *supra* note 8. Section III, Terms and Conditions, of the Grant Award, would be the obvious section in which to require compliance with FACA requirements.

[144] Federal Advisory Committee Act of 1972 § 3, 5 U.S.C.A. App. 2 (2019).

[145] S. REP. NO. 92-1098, at 5–6 (1972).

[146] *Id.* at 5.

[147] *Id.* at 14.

[148] *Id.*

[149] *Id.* at 6.

entities, entities which the U.S. government "helped bring into being."[150] IARC and its Monograph Program are emblematic of a quasi-public entity, as evidenced by the close and ongoing financial and programmatic partnership IARC has enjoyed with the U.S. government, through the NCI and other governmental agencies.[151]

The recently updated Preamble to the Monographs does not include opportunities for public comment during the working group meetings or opportunities to review any draft Monograph related materials produced either by the IARC staff or working group members.[152] In short, the working groups remain insular, precisely the ailment that FACA was meant to cure.[153]

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[150] Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 463 (1989).
[151] *See* GRANT APPLICATION, *supra* note 8, at 3–5.
[152] *See* PREAMBLE, *supra* note 26, at 5–6.
[153] The 1997 amendments to the Federal Advisory Committee Act limited its application to the National Academy of Sciences and the National Academy of Public Administration. Federal Advisory Committee Act Amendments of 1997, § 2(a) Stat. 2689. The amendments, therefore, did not address "other entities outside the Federal government [that] might subsequently be deemed 'quasi-public' and thus subject to FACA." 143 CONG. REC. H10,578-02, 5 (1997).