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May 1, 2009

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RE: Legislative History of the *Report on Carcinogens* and its Relevance to Styrene

Dear Dr. Birnbaum:

Recently, both the American Composites Manufacturers Association and the National Marine Manufacturers Association wrote to you proposing an alternative administrative approach to including styrene in the *Report on Carcinogens (RoC)* – i.e., that styrene not be classified and listed in the report as “reasonably anticipated to be a human carcinogen,” but still be referenced in the *Report*. Additionally, Drs. Bus and Cruzan, in an April 29 letter to you, further recommended that the *RoC* could present styrene as having been assessed as a substance that should appropriately be considered as providing “suggestive evidence” of carcinogenic potential, but which could not accurately be listed as “reasonably anticipated” to be a carcinogen. Their letter further cited comments from members of the February 24, 2009 NTP Board of Scientific Counselors meeting that supported such a conclusion.

Knowing that, as Director of NIEHS, it is your desire to ensure that every chemical, including styrene, is objectively treated in the *RoC*, The Styrene Information and Research Center¹ (SIRC) undertook to determine whether there are legislative impediments to NTP treating styrene in the manner suggested by these aforementioned organizations and scientists. The language of the statute authorizing the *RoC* is relatively brief and, while the statutory phrase “reasonably anticipated to be a human carcinogen” uses straightforward language, the meaning within the scientific context of carcinogen classification is neither elementary nor clear. We therefore examined the legislative history leading to the passage of this provision to clarify Congressional intent.

¹ The Styrene Information and Research Center’s (SIRC’s) mission is to evaluate existing data on potential health effects of styrene, and develop additional data where it is needed. SIRC has gained recognition as a reliable source of information on styrene and helping ensure that regulatory decisions are based on sound science. For more information, visit <http://www.styrene.org>.

The legislative history is quite revealing. It provides very helpful guidance on the interpretation of the phrase “reasonably anticipated to be a human carcinogen,” and it does not contain language that could be interpreted as an impediment to the recommendations you received urging NTP to include additional findings about particular substances in the RoC. We therefore conclude, and commend to your attention, that the legislative history of the statute authorizing the RoC provides NTP with the flexibility to address styrene objectively, as discussed in this communication.

Enclosed with this letter is a memorandum on the legislative history of the statutory provisions for the RoC, as compiled for SIRC by the law firm of Keller and Heckman, LLP. We are sure that you and your staff will want to review this legislative history carefully in order to confirm the conclusions presented herein. In particular, I want to call to your attention to a statement in the Joint House-Senate Comparative Summary, which states:

... the phrase ‘suspected carcinogens’ [was replaced] with ‘substances...reasonably anticipated to be carcinogens,’ in order to make it absolutely clear in the statute that there must be reasonable ground for designating a substance as a putative carcinogen.²

The final legislative language was a clear departure from earlier proposals that would have expansively listed substances as suspect carcinogens based on much looser criteria, for example, “sound theoretical grounds.”³ As discussed in the accompanying memorandum, the legislative history preceding this change by the Conference Committee focused on coordinating regulatory activity across the federal government as well as public communication. Subsequently, Representative Paul G. Rogers, a key Congressman in the legislative process for the RoC, described the regulatory importance of the Annual Report:

The intention of the legislation was that listing in the annual report would be a first step in regulation, one triggering a review by the agencies responsible for enforcing various laws regulating carcinogens.⁴

From this regulatory perspective, it is obviously prudent to avoid the adverse impact, including misdirection of governmental resources and potential costs imposed on society that are associated with a government classification (and subsequent regulation) of a substance as a carcinogen unless there is a high degree of scientific assurance that such action was warranted.

The legislative history also associates public education with regard to the creation of a *Report on Carcinogens*. Thus, another purpose in changing the legislative language from “suspected” to “reasonably anticipated” appears to have been intended to focus public attention on substances for which the science provided a *high degree of assurance* that a human cancer characterization was merited. Thus, the legislative history surrounding the “reasonably anticipated” language provides very helpful guidance regarding the “lower

² Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

³ 124 CONG. REC. H34938 (1978) (statement of Rep. Rogers).

⁴ Rogers, P., quoted in Occupational Health & Safety Letter (May 22, 1987).

boundary” of the categorization -- a boundary that perhaps has, in practice, taken on a more loosely defined character over the years as the *RoC* statute has been implemented.

Secondly, a review of the legislative history and the statutory language demonstrates that there is no guidance from Congress that prohibits or discourages including in the *RoC* statements about substances that, once reviewed, were determined not to meet the criteria for classification in the *RoC* as “known” or “reasonably anticipated” carcinogens, but for which further information for other government agencies and the public would be helpful, such as scientific findings that the available research does not support giving a substance an entirely “clean bill of health.” This could be an addition to Appendix C that is already a routine part of the *RoC*.

In summary, SIRC’s assessment of this legislative history indicates there is no statutory prohibition on NTP addressing the characterization of styrene by including styrene in the report and appropriately characterizing it as of lesser or indeterminate carcinogenic concern (e.g., as providing only “suggestive evidence”). The “reasonably anticipated” language was employed in the final legislation to avoid the anticipated adverse impact associated with a federal classification as a carcinogen (which could be quite severe for the styrene-using industries), unless there was a high degree of assurance that such a listing was scientifically merited. SIRC’s suggestion of characterizing styrene as appropriately classified in a lesser category would avoid just such an impact and would be consistent with Congress’ original intent.

We believe that exercising the option to describe the database for styrene as containing “suggestive evidence” or a similar description in the 12th *RoC* would reflect a significant advancement of the *RoC* process; one that would enhance the accuracy and credibility of the Report, and which is scientifically supported by the comments of the NTP Board of Scientific Counselors. SIRC urges that you give strong consideration to an alternative treatment of styrene as NTP finalizes the Styrene Substance Profile, and moves to complete the 12th *RoC*.

In closing, SIRC asks that this letter be made part of the public record by its inclusion in the styrene docket for the 12th *Report on Carcinogens*.

Very truly yours,

[Redacted]

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MEMORANDUM

To: Jack Snyder, SIRC
From: Peter de la Cruz
Date: April 23, 2009
Re: Report on Carcinogens – Legislative History

This memorandum reviews the legislative history underlying the creation of the *Report on Carcinogens*, which is now issued every few years by the National Toxicology Program.

A. OVERVIEW AND COMMENTARY

In 1937, Congress enacted The National Cancer Institute Act of 1937 (Public Law 75-244), which established the National Cancer Institute (NCI) and authorized NCI to conduct research on the origins and treatment of cancer.¹ With the enactment of The National Cancer Act of 1971, the federal government implemented an expanded research program in an effort to reduce and eliminate the incidence of cancer in the United States. Despite the aspirations surrounding the enhanced government research effort, by the late 1970s, it was evident that a cure for cancer was not imminent. Against this backdrop, a revised national cancer strategy was proposed that supplemented cancer research with cancer prevention measures.

While the House was the initial source of legislation seeking to create a *Report on Carcinogens*, it was a subsequent Senate bill (S. 2450) that was adopted in lieu of H.R. 12347, and enacted as Public Law 95-622.² The Senate bill made several changes to the provision requiring the Report on Carcinogens, as explained in the *Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute*.³

¹ The National Cancer Institute Act of 1937, <http://www.cancer.gov/aboutnci/national-cancer-act-1937>. Some sources refer to the Act as the “National Cancer Act of 1937.” National Cancer Act of 1937, <http://legislative.cancer.gov/history/1937>.

² Biomedical Research and Research Training Amendments of 1978, 42 U.S.C. 241(b)(4) (1978).

³ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38653 (1978) (statement of Rep. Rogers).

Unlike the House bill, the Senate bill added the Annual Report requirement to section 301 of the Public Health Services Act, and assigned responsibility for the Annual Report to the Department of Health, Education, and Welfare.⁴ Additionally, while the House bill referred to “suspected carcinogens,” the Senate bill changed the term to “substances . . . reasonably anticipated to be carcinogens:”

Other changes include a replacement of the phrase “suspected carcinogens” with “substances . . . reasonably anticipated to be carcinogens,” in order to make it absolutely clear in the statute that there must be reasonable ground for designating a substance as a putative carcinogen.⁵

The final legislative language was a clear departure from earlier proposals that would have expansively listed substances as suspect carcinogens based on much looser criteria, for example, “sound theoretical grounds.”⁶

The legislative history preceding this change by the Conference Committee focused on coordinating regulatory activity across the federal government as well as public communication. Subsequently, Congressman Paul Rogers, a sponsor of the legislation, described the regulatory importance of the Annual Report:

The intention of the legislation was that listing in the annual report would be a first step in regulation, one triggering a review by the agencies responsible for enforcing various laws regulating carcinogens.⁷

From a regulatory perspective, it is prudent to avoid the adverse impacts of misdirection of governmental resources and costs imposed on society that are associated with a government classification as a carcinogen and subsequent regulation unless there is a high degree of assurance that such a characterization is warranted.

The legislative history also associates public education with the creation of a *Report on Carcinogens*. Another purpose in changing the legislative language from ‘suspected’ to ‘reasonably anticipated’ appears to have been intended to focus public attention on substances for which the science provided a high degree of assurance that a human cancer characterization was merited. Thus, the legislative history surrounding the ‘reasonably anticipated’ language provides very helpful guidance regarding the “lower boundary” of the categorization.

⁴ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

⁵ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

⁶ 124 CONG. REC. H34938 (1978) (statement of Rep. Rogers).

⁷ Rogers, P., quoted in Occupational Health & Safety Letter (May 22, 1987).

There is no express statement that we could locate in the legislative history that prohibits NTP from expanding the Report to include descriptions of substances that were reviewed by NTP, did not meet the criteria for listing, but still deserve mention in terms of suggestive evidence regarding their carcinogenicity. Therefore, we believe that NTP has the flexibility to add such descriptions to the report if it chooses to do so in the interest of better informing the Report's readers.

B. LEGISLATIVE HISTORY

In 1937, Congress enacted The National Cancer Institute Act of 1937 (Public Law 75-244), which established the NCI and made it the federal government's principal agency for conducting research and training on the cause, diagnosis, and treatment of cancer.⁸ In the early 1970s, an intensified focus on cancer prompted legislation to expand cancer research. Congress enacted The National Cancer Act of 1971 (Public Law 92-218, codified under Title IV of the Public Health Service Act) in response to an alarming increase in the incidence and death rate due to cancer.⁹ The Act required the Director of the NCI to develop a National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.¹⁰

In the late 1970s, Congress turned its attention to cancer once more. On November 4, 1977, Rep. Harley Staggers introduced House bill 10062, "A bill to amend Title V of the Public Health Service Act to Provide for Cancer Research Awards." On December 1, 1977, Rep. Andrew Maguire introduced House bill 10190, also known as the "Cancer Prevention Act of 1978." H.R. 10190 contained a provision requiring the NCI Director to publish an annual report containing a list of carcinogens.

The Director of the National Cancer Institute shall publish an annual report which contains—

- (1) a list of all known or suspected carcinogens to which a significant number of persons residing in the United States are exposed;
- (2) information concerning the nature of such exposure and the estimated number of persons exposed to such carcinogens; and
- (3) an evaluation of the efficacy of the existing regulatory controls designed to reduce or eliminate exposure to carcinogens, and recommendations respecting ways in which such controls could be improved.¹¹

⁸ National Cancer Act of 1937, <http://legislative.cancer.gov/history/1937>.

⁹ H.R. REP. NO. 95-1192, at 17 (1978).

¹⁰ H.R. REP. NO. 95-1192, at 17 (1978). The National Cancer Act of 1971, <http://legislative.cancer.gov/history/phsa/1971>. NCI Research Overview, <https://icrc.nci.nih.gov/ResearchAreas.html>.

¹¹ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 28 (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf.

Rep. Paul G. Rogers introduced House bill 10908 on February 9, 1978. The bill extended funding for programs of NCI, the Libraries of Medicine, the Blood Institute and the National Heart, Lung, and Blood Institute. All three bills were referred to the House Committee on Interstate and Foreign Commerce.

1. *March 1978 House Hearings*

During March 1-3, 1978, the Health and Environment Subcommittee¹² of the House Committee on Interstate and Foreign Commerce held a hearing on the three bills.¹³ Some consider this the first public presentation of the concept of a comprehensive Annual Report.¹⁴ In light of the growing concern about environmental carcinogens, witnesses testified about the need for a comprehensive list of all known or suspected carcinogens that could be made available to the public.¹⁵ Rep. Maguire discussed his proposal in H.R. 10190 for a comprehensive report on carcinogens.

Why should we not have an annual report, a requirement that we have a report each and every year from NCI with respect to all known and suspected carcinogens, estimating the dangers and making some assessment of the exposures, and making an evaluation of the existing regulatory situation and recommendations? (Statement of Rep. Maguire.)¹⁶

At the hearing, witnesses also discussed NCI's progress on cancer research, biomedical research and research training, and the national strategy on cancer.¹⁷ Witnesses at the hearing

¹² In 1978, the Health and Environment Subcommittee was a part of the House Committee on Interstate and Foreign Commerce. In 1981, the Committee on Interstate and Foreign Commerce was changed to the Committee on Energy and Commerce. As of early 2001, the Committee on Energy and Commerce included the Health and Environment Subcommittee, the Finance and Hazardous Materials Subcommittee, and the Energy and Power Subcommittee. In mid-2001, these subcommittees were reorganized into the Health Subcommittee, the Environment and Hazardous Materials Subcommittee, and the Energy and Air Quality Subcommittee. In early 2009, these subcommittees were once again reorganized into the Health Subcommittee, and the Energy and Environment Subcommittee.

¹³ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf.

¹⁴ OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 171 (U.S. Government Printing Office 1987), *available at* <http://www.princeton.edu/~ota/disk2/1987/8711/8711.PDF>.

¹⁵ H.R. REP. NO. 95-1192, at 21 (1978). OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 171 (U.S. Government Printing Office 1987), *available at* <http://www.princeton.edu/~ota/disk2/1987/8711/8711.PDF>.

¹⁶ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 52 (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf (statement of Rep. Maguire).

¹⁷ H.R. REP. NO. 95-1192, at 21 (1978). OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 171 (U.S. Government Printing Office 1987), *available at* <http://www.princeton.edu/~ota/disk2/1987/8711/8711.PDF>.

stressed a more preventive approach to tackling cancer that involved (1) more research on cancer-causing agents, and (2) dissemination of information to the public.¹⁸ Dr. Joseph Highland, then chairman of the toxic chemical program of the Environmental Defense Fund, public interest representative to the NCI, and member of the National Clearinghouse on Chemical Carcinogenesis, stated:

I cannot stress enough how vitally important it is that a clear and definitive emphasis on cancer prevention rather than cancer cure become the primary objective of the NCI. In a time of limited resources, more emphasis must be placed on truly preventive action. (Statement of Dr. Highland.)¹⁹

Dr. Irving Selikoff, then Director of the Environmental Sciences Laboratory of the Mount Sinai School of Medicine, stated:

[I] would like to spend a few moments stressing my evaluation of two very important questions that might be considered by your committee in its analysis of the renewal of the National Cancer Act.

I refer to the importance of prevention, and the potential for such renewal and orientation, shall I say reorientation, on the part of the National Cancer Institute in this regard.²⁰

Several witnesses also emphasized the importance of understanding environmental carcinogens and urged an expansion of research programs on environmental carcinogenesis.²¹ Written testimony was submitted on cancer prevention through identification of environmental carcinogens.

Most scientists believe that environmental factors—chemicals, radiations, and possibly viruses, all playing a role in one or another instance—interact with hereditary information in cells to produce a complex sequence of events that lead to development of cancer.

Thus, most cancers are theoretically preventable, if we identify causative agents, and avoid them, eliminate them from the environment, or modify the individual's response to them, or reverse or arrest the biological effects that may result in

¹⁸ H.R. REP. NO. 95-1192, at 17, 21 (1978).

¹⁹ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 174 (1978), available at http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf (statement of Dr. Highland).*

²⁰ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 171-72 (1978), available at http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf (statement of Dr. Selikoff).*

²¹ H.R. REP. NO. 95-1192, at 21 (1978).

cancer. Extensive research is needed before it will be possible to prescribe practical steps for preventing the cancer-causing action of environmental factors.²²

The testimony also explained that the NCI was heavily involved in educational efforts. For example, the NCI had established prevention projects for workers exposed to asbestos and vinyl chloride, which provided health education to the workers and their families to ensure early detection of precancerous lesions and early cancer.²³ The NCI also made efforts to educate physicians about the risks of various cancers, and to use the media to encourage persons at high risk of developing cancer to seek screening.²⁴

On April 18, 1978, the Subcommittee on Health and Environment considered and amended H.R. 10908, and ordered the bill reported as the clean House bill 12347. Later that month, Rep. Paul Rogers introduced H.R. 12347, which consolidated H.R. 10190 and H.R. 10908.²⁵

2. *House Bill 12347*

On April 25, 1978, Rep. Paul Rogers introduced to the House H.R. 12347, which provided for, *inter alia*, an annual report containing a list of carcinogenic chemicals. The Report of the Committee on Interstate and Foreign Commerce (report) discusses H.R. 12347 in the context of national efforts to combat cancer, explaining that the bill was intended to bolster cancer research through the National Cancer Program.²⁶

The report echoes witness testimony from the hearing of the Health and Environment Subcommittee, stressing the same preventive measures to combat cancer, including identifying environmental carcinogens.²⁷ Expanding on the testimony about the preventive role of education, the report calls for educational programs to teach the public about factors that increase the risk of cancer, and how to avoid them.²⁸ The report also calls for specific education and

²² *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 65 (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf.

²³ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 83 (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf.

²⁴ *Biomedical Research and Research Training Amendments of 1978: Hearing on H.R. 10908, H.R. 10062, and H.R. 10190, Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce H.R., 95th Cong. 84 (1978), available at* http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/38/c6/8c.pdf.

²⁵ Our sources do not explain exactly how the Subcommittee dealt with H.R. 10190 and H.R. 10062. However, it is clear that H.R. 12347 contained elements of H.R. 10908 and H.R. 10190, but not H.R. 10062.

²⁶ H.R. REP. NO. 95-1192, at 17 (1978).

²⁷ H.R. REP. NO. 95-1192, at 9, 17, 19 (1978).

²⁸ H.R. REP. NO. 95-1192, at 19 (1978).

demonstration programs for health professionals, in methods of early detection and improved methods of patient referral for early diagnosis.²⁹

It was particularly stressed by several witnesses that to continue and strengthen programs in basic biomedical research is of the utmost importance, and to provide trained research personnel to continue the U.S. high quality of research is also essential. Moreover, much greater emphasis on preventive approach by NCI is needed.

...

[T]he institute should place emphasis on education of health professionals and the general public concerning the factors that apparently lead to a higher risk of cancer, and ways to avoid them. It further believes that NCI should continue and substantially expand its research into identifying agents in the indoor and outdoor environment which may lead to a cancerous state. Increased attention to the environmental causes of cancer is essential for an effective preventive approach under the national cancer program.

...

The committee considered there to be two major areas for which statutory changes were required. These are (1) an emphasis on education and demonstration programs, particularly for those treating patients with cancer or advising individuals how to avoid cancer, and (2) the direction to NCI to devote substantially more resources to prevention, focusing particularly on the importance of environmental, dietary, and occupational causes of cancer.

...

The importance of environmental carcinogenesis and the necessity to control it was expressed by Dr. Highland and Dr. Selikoff, who testified at the subcommittee's hearings on biomedical research and training in March 1978. Both of these scientists stated that it was their belief that a much more effective use of the Institute's resources would be realized if programs of research and prevention concerning cancer caused by environmental sources could be expanded. Their recommendations included making available to the public a list of all known or suspected carcinogens, an expansion of research programs in environmental carcinogenesis including the bioassay program, a study of the feasibility of establishing a national data bank to identify those individuals at high risk of cancer, and the importance of stressing environmental, dietary, and occupational exposure to carcinogens in public education programs and continuing education programs for physicians and other personnel involved in health care delivery.³⁰

²⁹ H.R. REP. NO. 95-1192, at 26-27 (1978).

³⁰ H.R. REP. NO. 95-1192, at 18-21 (1978).

3. *The Annual Report on Carcinogens under House Bill 12347*

H.R. 12347 proposed to amend The National Cancer Act of 1971 (Public Law 92-218, codified under Title IV of the Public Health Services Act) by requiring that the NCI Director publish an *Annual Report on Carcinogens*.³¹ The Annual Report was to include:

- A. a list of all “known or suspected carcinogens” to which a significant number of persons residing in the United States are exposed;
- B. information concerning the nature of such exposure and the estimated number of individuals exposed to such carcinogens; and
- C. an evaluation of the efficacy of the existing regulatory standards designed to reduce or eliminate exposure to carcinogens, and recommendations respecting ways in which such standards could be improved.³²

The report describes the information the Committee intended the Annual Report to contain:

An additional amendment mandates the Director of NCI to publish an annual report which contains a list of all known or suspected carcinogens to which significant number of persons in the United States are exposed. This report must include information concerning the nature of such exposure and the estimated number of persons exposed to such carcinogens.

...

The committee intends that [the *Annual Report on Carcinogens*] should be a comprehensive document containing an updated list of all known or suspected carcinogenic agents, the nature of exposure and the approximate number of persons exposed to such agents. The relative toxicity of such agents should be described, to the extent such information is known, whether or not any of these act synergistically, the levels of exposure to be expected from certain occupations, geographic areas, foods or consumer goods, and the identification of subpopulations expected to be at higher than average risk (for example, workers in chemical plants in Wilmington, Del.; U.S. servicemen participating in nuclear weapons tests, or those eating catfish from the lower Mississippi containing high levels of chlorinated hydrocarbon pesticide residues). The report should also contain information to assist the reader to reduce subsequent exposure to such agents. It is the committee’s intent that the report include a description of or references to the data which led to NCI’s conclusion that a particular substance be included on the list, including the basis for a substance being either a suspected or confirmed carcinogen.³³

The Congressional Record provides additional details:

³¹ H.R. REP. NO. 95-1192, at 53 (1978).

³² H.R. REP. NO. 95-1192, at 53 (1978).

³³ H.R. REP. NO. 95-1192, at 22-23, 28 (1978).

[T]he requirement in the amendments to the National Cancer Act that the Director of NCI publish an annual report containing “a list of all known or suspected carcinogens to which a significant number of persons residing in the United States are exposed” has raised the question of on what basis a substance is either “known” or “suspected,” and, if so, suspected by whom. While this provision is discussed in some detail on page 28 of the committee report, additional clarification is included here.

It is the committee’s intent that any such list include not only the name of the substance, but the data which supports the inclusion of each compound on the list, any uncertainties in the data yet to be resolved, and where possible, estimates the magnitude of the risk each poses. This list should include any compound as “suspect” for which there may be, for example, sound theoretical grounds for suspecting that it may have carcinogenic potential, such as a stereoisomer [*sic*] of a known carcinogen, or data showing it to be mutagenic in bacteria. However, the nature of all such supporting data must be included in the report. The report should be properly organized so that no possible confusion could exist between clearly demonstrated carcinogens and those for which convincing data are not yet available to the Director of NCI, information concerning the relative risk posed by each substance and the quality of the data will be made unequivocally [*sic*] clear to the reader.

Suggestions that such a list include only those compounds demonstrated to be carcinogenic in man—through epidemiological studies—or in the animals by direct test were rejected as being too limited, in that definitive animal or human data does not exist for large numbers of substances for which there are many grounds for suspecting carcinogenic properties. The committee believes that cases where synergistic [*sic*] effects have been shown between two or more compounds also be discussed in the Director’s report. (Statement of Rep. Rogers.)³⁴

H.R. 12347 also required the NCI Director to assess existing regulatory standards for substances included in the Annual Report. If a substance identified as carcinogenic was not regulated, or inadequately regulated, the Director would be responsible for alerting the appropriate regulatory agency.³⁵ In the case of existing but inadequate regulatory standards on carcinogens, the Director would also be required to recommend specific ways in which these standards could be improved.³⁶

The requirement that the Director evaluate the efficacy of existing regulatory standards should, in the event that a substance has been identified as carcinogenic and is not currently regulated or is not adequately regulated, bring this to the attention of the appropriate regulatory agency so that it may take prompt action.

³⁴ 124 CONG. REC. H34938 (1978) (statement of Rep. Rogers).

³⁵ H.R. REP. NO. 95-1192, at 22 (1978).

³⁶ H.R. REP. NO. 95-1192, at 22 (1978).

Clearly, in order to effectively prevent cancer and reduce the exposure of the public to such agents, there will have to be extensive cooperation between the research agencies . . . that is, the National Institutes of Health, particularly the National Cancer Institute, and the various regulatory agencies which under the committee bill would be represented by ex-officio members on the National Cancer Advisory Board.

. . . .

An important deterrent in the exposure of individuals to carcinogenic agents is the effectiveness of the various regulatory authorities established to reduce or eliminate exposure of individuals to harmful substances or agents. Therefore, the committee requires the Director of the National Cancer Institute to include in this annual report an evaluation of the efficacy of appropriate existing regulatory standards, and recommendations regarding the need to improve these standards. This report should evaluate not only the effectiveness and degree of protection afforded by the standards themselves, but also the adequacy of the way such standards are being administered and enforced.³⁷

According to Rep. Rogers, the intent of the legislation was that “listing in the annual report would be a first step in regulation, one triggering a review by the agencies responsible for enforcing various laws regulating carcinogens.”³⁸

4. *The Senate bill*

S. 2450 was adopted in lieu of H.R. 12347, and enacted as Public Law 95-622.³⁹ Unlike the House bill, the Senate bill added the Annual Report requirement to section 301 of the Public Health Services Act, and assigned responsibility for the Annual Report to the Department of Health, Education, and Welfare.⁴⁰

While the House bill referred to “suspected carcinogens,” the Senate bill changed the term to “substances . . . reasonably anticipated to be carcinogens.”

Other changes include a replacement of the phrase “suspected carcinogens” with “substances . . . reasonably anticipated to be carcinogens”, in order to make it absolutely clear in the statute that there must be reasonable ground for designating a substance as a putative carcinogen.⁴¹

³⁷ H.R. REP. NO. 95-1192, at 22-23, 28 (1978).

³⁸ OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 171-72 (U.S. Government Printing Office 1987), available at <http://www.princeton.edu/~ota/disk2/1987/8711/8711.PDF>.

³⁹ Biomedical Research and Research Training Amendments of 1978, 42 U.S.C. 241(b)(4) (1978).

⁴⁰ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

⁴¹ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

The Senate also changed the provision in the House bill requiring an evaluation of existing regulatory standards on a substance listed in the Annual Report:

The provision previously requiring an evaluation of existing regulatory standards for efficacy has been modified to require a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient or exposure standards has been established by a Federal agency, and (ii) for each existing standard, the extent to which, on the basis of available data, such standard and its implementation by the appropriate agency, decreases the risk to public health.⁴²

Finally, the Senate added a provision requiring the report to include a description of each request from a Federal agency to conduct research or testing concerning the carcinogenicity of substances, and the response to each such request.⁴³

Rep. Andrew Maguire and Rep. Paul Rogers both believed that the changes made by the Senate did not alter the intent of the original legislation.⁴⁴

C. CHRONOLOGY OF EVENTS

- August 5, 1937** The National Cancer Institute Act of 1937 is enacted as Public Law 75-244.
- December 23, 1971** The National Cancer Act of 1971 is enacted as Public Law 92-218.
- November 4, 1977** Rep. Harley Staggers introduces in the House H.R. 10062 ("A bill to amend Title V of the Public Health Service Act to Provide for Cancer Research Awards"). The bill is referred to the House Committee on Interstate and Foreign Commerce.
- December 1, 1977** Rep. Andrew Maguire introduces in the House H.R. 10190 ("Cancer Prevention Act of 1978"). The bill is referred to the House Committee on Interstate and Foreign Commerce.
- January 27, 1978** Sen. Edward Kennedy introduces S.2450 in the Senate.
- February 9, 1978** Rep. Paul Rogers introduces in the House H.R. 10908 ("Biomedical Research and Research Training Amendments of 1978"). The bill is

⁴² Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657 (1978) (statement of Rep. Rogers).

⁴³ Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute. 124 CONG. REC. H38657-58 (1978) (statement of Rep. Rogers).

⁴⁴ OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, IDENTIFYING AND REGULATING CARCINOGENS 172 (U.S. Government Printing Office 1987), available at <http://www.princeton.edu/~ota/disk2/1987/8711/8711.PDF>.

- referred to the House Committee on Interstate and Foreign Commerce.
- March 1-3, 1978** Hearing of the House Subcommittee on Health and Environment on H.R. 10062, H.R. 10190, and H.R. 10908. An annual report on carcinogens is first publicly proposed.
- April 3, 1978** The Subcommittee on Health and Scientific Research considers S.2450 and orders the bill reported to the Senate Committee on Human Resources.
- April 18, 1978** The Subcommittee on Health and Environment considers and amends H.R. 10908, and orders the bill reported as a clean bill, H.R. 12347.
- April 25, 1978** Rep. Paul Rogers introduces in the House H.R. 12347, which is referred to the House Committee on Interstate and Foreign Commerce.
- April 28, 1978** The Senate Committee on Human Resources considers S.2450 and orders the bill reported to the Senate.
- May 2, 1978** House Committee on Interstate and Foreign Commerce considers H.R. 12347.
- May 15, 1978** H.R. 12347 is reported to the House from the Committee on Interstate and Foreign Commerce. *House Report (Interstate and Foreign Commerce Committee) No. 95-1192.* S.2450 is reported to the Senate from the Committee on Human Resources. *Senate Report (Human Resources Committee) No. 95-838.*
- June 26, 1978** S.2450 is considered and passed in Senate.
- June 28, 1978** S.2450 is referred to House Committee on Interstate and Foreign Commerce.
- October 10, 1978** H.R. 12347 is considered in House.
- October 14, 1978** S.2450 passes in the House in lieu of H.R. 12347 and H.R. 12460.⁴⁵ Senate agrees to House amendments and passes S.2450. *Joint House-Senate Comparative Summary and Explanation of Title II of H.R. 12460 and H.R. 12347, as Reported by the Committee on Interstate and Foreign Commerce, the Senate Bill, S. 2450, and the House Amendment in the Nature of a Substitute.*
- November 9, 1978** President Carter signs Public Law 95-622.

⁴⁵ H.R. 12460 contained the Health Centers Amendments of 1978, which extended programs under the Community Mental Health Centers Act. S. 2450 consolidated H.R. 12460 and H.R. 12347, with H.R. 12460 renamed as the Community Mental Health Centers Extension Act of 1978. Thus, Title I of Public Law 95-622 consists of the Community Mental Health Center Extension Act of 1978, while Title II consists of the Biomedical Research and Training Amendments of 1978.