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## OSHA's Four Inconsistent Carcinogen Policies

### Background

No issue has proven more contentious in occupational health policy than the control of chemical carcinogens. The Occupational Safety and Health Administration (OSHA) has focused much of its efforts on cancer risks, both through substance-specific regulations and through broader efforts to establish generic policies and work practices. The 1980 Generic Carcinogen Policy was conceptualized as the centerpiece of OSHA's shift from substance-specific to generic regulations covering hundreds if not thousands of substances. Despite adverse judicial rulings and a generally anti-regulatory political climate, OSHA continued to pursue a generic approach to occupational health hazards during the 1980s, particularly through its 1983 Hazard Communication Standard and 1989 Air Contaminants Standard. The legal and political wrangling have left deep scars on OSHA's strategy, however. While consistency and comprehensiveness were once the principles underlying OSHA's efforts to control carcinogens, the current collection of policies and regulations is remarkable for the inconsistent and incomplete way in which suspect chemicals are treated.

In this paper, we analyze OSHA's four carcinogen strategies, as embodied in the Generic Carcinogen Policy, the substance-specific carcinogen regulations, the Hazard Communication Standard, and the Air Contaminants Standard. Two issues are of particular interest.

• Given the inherent methodological limitations to epidemiological data on occupational and environmental cancer, a

major scientific and policy debate has developed over the appropriate use in human risk assessment of laboratory evidence on chemical carcinogenesis in animals. The four OSHA policies exhibit quite different positions on this debate.

• The choice between direct regulation and indirect labor market pressure, and the stringency of those exposure limits that are imposed, reflect different attitudes toward the appropriate balance of economic costs and health benefits for occupational health regulations. OSHA's four policies reflect dramatically different balancing efforts.

We begin with the Generic Carcinogen Policy, which remains OSHA's formal policy on the issue but which has been blocked by administrative stays and never incorporated into risk management programs. The substance-specific cancer standards are then analyzed in terms of their comprehensive treatment of a few public health hazards and neglect of many others. While partially an attempt to preempt stronger state and local regulations, the Hazard Communication Standard is in many ways both comprehensive and innovative, covering a wide range of chemicals and imposing duties on employers that could potentially lead to substitution of alternative products and processes. Given its current prominence as the centerpiece of OSHA's regulatory program, the Air Contaminants Standard receives the greatest emphasis. Containing its own internal inconsistencies, the Air Contaminants Standard embodies the best and the worst of OSHA's new regulatory philosophy and its strategy for controlling chemical carcinogens in the workplace.

### *The Generic Carcinogen Policy*

OSHA's Generic Carcinogen Policy<sup>1</sup> was a response to two complementary

concerns that emerged over the course of the 1970s and came to dominate the agency's agenda. OSHA had devoted a substantial portion of its resources to the regulation of individual carcinogens but had achieved only meagre results. The agency leadership faced growing demand for an accelerated regulatory timetable from Congress, organized labor, and environmental groups. Of equal significance, perhaps, was the competition among several federal agencies for leadership in formulating governmental policies with respect to chemical carcinogens. Proposed in 1977 and promulgated in 1980, OSHA's Generic Carcinogen Policy embodied a highly protective approach to chemical carcinogenesis. Based on the most conservative set of assumptions concerning methods of cancer induction and the most stringent set of requirements for exposure controls, the 1980 policy represents the high water mark of governmental enthusiasm for regulating occupational and environmental carcinogens.

OSHA devoted much of its energies during the 1970s to developing standards regulating exposure to occupational carcinogens, including asbestos<sup>2</sup> in 1972, vinyl chloride<sup>3</sup> and a group of 14 chemicals<sup>4</sup> in 1974, coke oven emissions<sup>5</sup> in 1976, plus benzene,<sup>6</sup> dibromochloropropane (DBCP),<sup>7</sup> inorganic arsenic,<sup>8</sup> and acry-

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lonitrile<sup>9</sup> in 1978. All of these except the DBCP and acrylonitrile standards underwent court challenges from the regulated industries, with lengthy delays and threats of reversal. A number of "science policy" issues reappeared at each challenge, including the relevance of animal data for human carcinogenesis, the importance of negative study results compared to positive results, the correlation between induction of benign and malignant tumors, and the purported existence of a threshold for carcinogenic effects. These same policy issues were being raised at EPA with respect to pesticides covered by the Federal Insecticide, Fungicide, and Rodenticide Act<sup>10</sup> and toxic air pollutants covered by the Clean Air Act.<sup>11</sup> After some discussions with EPA over the possibility of a joint carcinogen policy, OSHA decided to proceed with its own standard. The history of the OSHA policy and its relationship with initiatives at other regulatory agencies has been described in detail in several publications.<sup>12-17</sup>

The Generic Carcinogen Policy established a categorization system for known or suspected chemical carcinogens, with immediate regulatory action being proposed for substances falling into Category I. This category would be composed of substances that increased the incidence of benign or malignant tumors or decreased the latency period between exposure and onset in humans, in two animal species, in a single mammalian species in two or more independent experiments, or in a single experiment if supported by evidence from short-term tests. Within the universe of substances falling into Category I, the policy established a priority setting mechanism whereby the agency would select 10 substances for comprehensive standard setting at any one time, to include requirements for exposure limits, monitoring, worker training, and other factors. In 1980, OSHA issued a candidate list of 204 chemicals for review as possible candidates under the terms of the policy. The exposure limits were to be set at the lowest "feasible" level, which was interpreted by the agency as accepting any level of compliance costs short of causing massive economic dislocation and job loss in the regulated industry.

The weakening of the Generic Carcinogen Policy began almost as soon as it was promulgated. In July of 1980, the United States Supreme Court upheld the decision by the Fifth Circuit Court of Appeals to vacate the standard governing occupational exposure to benzene, on the grounds that OSHA had not proven that

exposures to benzene at the level regulated by the standard posed a "significant risk" to employees.<sup>18</sup> This ruling implied that any standard not demonstrating significant risk, presumably through the emerging quantitative risk assessment methodologies, would be overturned. The types of evidence sufficient to qualify chemicals for OSHA's Category I did not demonstrate "significant risk" without further analysis. In January of 1981, OSHA issued a revised Generic Carcinogen Policy that mandated a two-part approach to characterization of individual carcinogens.<sup>19</sup> An initial qualitative assessment would be made in accordance with the original categorization system. For each particular substance falling into Category I, an assessment would be made of whether current exposure levels constituted a significant risk. Those chemicals considered to pose such a risk would be regulated down to the lowest feasible level, as before.

Of greater import for the Generic Carcinogen Policy was the presidential inauguration several days later of Ronald Reagan. OSHA's cancer policy was listed by the new Administration's Task Force on Regulatory Relief as one of the first 27 regulations to be reconsidered due to their economic costs. On March 27, 1981, the Generic Carcinogen Policy amendments proposed in January were withdrawn in order to permit OSHA to "address alternatives that had not been fully considered."<sup>20</sup> The policy remained in abeyance from then on. In January of 1982, OSHA officially proposed a partial stay on the publishing of the Candidate and Priority Lists of chemicals<sup>21</sup>; this stay was promulgated a year later.<sup>22</sup>

These actions were largely of symbolic importance, since the agency was not pursuing the hazard identification and regulation provisions of the Generic Carcinogen Policy in any case. In August of 1986, the agency announced its intention to propose rulemaking to revise the standard, but did not follow up with any substantive initiative.<sup>23</sup> In February 1987, the Fifth Circuit Court of Appeals dismissed 16 petitions filed by industry and labor groups concerning various provisions of the Generic Carcinogen Policy on the grounds that nothing had happened in six years and hence that it could be considered dormant.<sup>24</sup> Nevertheless the Generic Carcinogen Policy has remained as OSHA's official policy.<sup>25</sup> The National Institute for Occupational Safety and Health (NIOSH) continues to propose lowest feasible level regulations for substances with

laboratory evidence of carcinogenicity, under the authority of the Generic Carcinogen Policy.<sup>26,27</sup> This implies that only a relatively simple administrative decision might be sufficient to revive the policy, a matter of concern for industry groups and the Reagan Administration as the election of 1988 approached. The industry-sponsored American Industrial Health Council and the federal Office of Management and Budget (OMB) both recommended that rulemaking be pursued by OSHA to officially excise the offensive parts of the policy.<sup>28,29</sup> The OMB was particularly harsh on OSHA for allowing the timetable of deregulation to slip, declaring its concern for the Reagan "legacy" and noting that "there is only so much time left." Nevertheless, no action was taken on the policy.

The Generic Carcinogen Policy represents OSHA's most aggressive initiative directed at occupational carcinogens. It embodies all the most conservative, health-protective assumptions about the biological process of carcinogenesis. Of greatest importance, it declares that regulation should proceed for those chemicals for which there exists laboratory but not yet epidemiological evidence of cancer effects. The policy weighs the costs and benefits of regulation in a manner strongly oriented toward regulation. OSHA's definition of "feasible" is a highly stringent one. While not unique in its adoption of this concept of feasibility, the Generic Carcinogen Policy stands out in its effort to expeditiously extend the principle to a sweeping array of chemicals.

### *Substance-Specific Regulations*

OSHA continued to promulgate substance-specific standards in the 1980s, but now with even less success than during the previous decade. The battles of the 1970s had produced three legal and institutional barriers to aggressive regulation of occupational carcinogens which continue to haunt the agency to the present.

- First, the Supreme Court's "significant risk" doctrine underlying the dismissal of the original benzene standard requires the agency to perform a detailed quantitative risk assessment for each candidate carcinogen.

- Second, industry concern over the economic costs of compliance contributed to the development of an increasingly rigorous set of requirements for the agency to estimate the economic impact of each proposed regulation. This requirement for economic studies originated with President Gerald Ford,<sup>30</sup> was extended by

President Jimmy Carter,<sup>31</sup> and culminated with President Reagan's requirement for formal cost-benefit analysis.<sup>32</sup> While OSHA's health standards are officially exempt from these cost-benefit requirements due to a Supreme Court ruling on the cotton dust standard,<sup>33</sup> the agency is required to produce rigorous analyses of the expected cost of compliance with its standards.

• Third, the regulatory strategy of the 1970s raised OSHA to a position of high visibility and vulnerability with respect to the Office of Management and Budget, which has interpreted its role as one of reining in a regulatory process gone amok.<sup>34</sup>

Given these impediments and the general anti-regulatory mood of the Reagan Administration, it is perhaps remarkable that OSHA completed any cancer regulations at all. Its record of achievement during the 1980s was quite modest, consisting of leftover business from the previous decade in the form of the revised benzene<sup>35</sup> and asbestos<sup>36</sup> standards plus the promulgation of two new regulations governing ethylene oxide<sup>37</sup> and formaldehyde.<sup>38</sup>

Two features characterize OSHA's new substance-specific regulations. First, they all cover substances for which there exists epidemiological evidence of carcinogenicity in worker populations. While this might charitably be interpreted as beginning at the top of a priority list similar to those produced by the Generic Carcinogen Policy, it actually constitutes a rejection of the guiding principle of the Generic Carcinogen Policy, namely that regulation should proceed based on animal evidence without waiting for epidemiological studies. The Generic Carcinogen Policy was consciously designed to make the transition from epidemiology to animal laboratory evidence as the basis for OSHA regulations; the similarity between the substance-specific regulations of the 1980s and their counterparts in the 1970s eloquently testifies to the failure of this transition. The substance-specific regulations also symbolize the abandonment of OSHA's efforts to provide leadership for the federal regulatory agencies. This role has now reverted to EPA, which has a carcinogen policy that relies heavily on animal evidence.<sup>39</sup> The second salient feature of the substance-specific regulations is their relative stringency. The permissible exposure limit was reduced by 90 percent in the cases of asbestos and benzene,

by 98 percent in the case of ethylene oxide, and by 66 percent in the case of formaldehyde.

### ***The Hazard Communication Standard***

The most important standard promulgated by OSHA during the 1980s was the Hazard Communication Standard,<sup>40</sup> which requires labeling of hazardous substances and the development of training programs for workers. While less stringent than the Hazard Identification Standard which was proposed by the Carter Administration<sup>41</sup> and withdrawn in the first months of the Reagan Administration,<sup>42</sup> the Hazard Communication Standard is nevertheless sweeping in scope and potentially significant in impact. Although not focused on carcinogens, the Hazard Communication Standard does impose important new obligations on producers and users of these substances.

The Hazard Communication Standard is officially a "performance standard" which delegates to industry management the right and responsibility to decide which substances are to be included in the labeling and training programs. Nevertheless, the Standard does provide a floor of substances that must be included. This includes chemicals listed as carcinogens by the International Agency for Research on Cancer (IARC) of the World Health Organization<sup>43</sup> plus chemicals included in the National Toxicology Program's (NTP) *Annual Report on Carcinogens*.<sup>44</sup> In addition, chemicals must be designated as potential carcinogens and included in worker training programs if they have produced evidence of carcinogenicity in any well-conducted laboratory studies. According to one estimate, these provisions mandate inclusion of 416 substances based on the IARC and NTP documents plus an additional 2,260 substances with laboratory evidence of carcinogenicity but which are not classified by IARC or NTP.<sup>45</sup> This broad scope of substances immediately evokes the Generic Carcinogen Policy, since it places laboratory data front and center in establishing which substances will be classified as potential occupational carcinogens. Less than 1 percent of these substances have strong epidemiological evidence of carcinogenicity in humans.

While similar to the Generic Carcinogen Policy in terms of scope, the Hazard Communication Standard differs markedly in terms of regulatory requirements.

It imposes no permissible exposure limits, much less ones that are the lowest feasible short of ruining the industry. Under the terms of the Standard, chemical manufacturers must prepare summaries of available toxicological and epidemiological information, in the form of a Material Safety Data Sheet (MSDS), and provide these to all purchasers of their products. Manufacturers are also responsible for the labeling of containers of hazardous substances; these labels contain brief warnings and refer to the relevant MSDS. All users of covered substances, not just chemical manufacturers, must develop written hazard communication programs that detail how they will comply with the Standard. These users must also organize worker training sessions which cover the information on the labels and MSDS plus proper handling procedures.

The Hazard Communication Standard provides no direct protections but relies upon worker responses to the new information for its ultimate efficacy. In principle, these responses could occur via turnover<sup>46-48</sup> or collective bargaining.<sup>49-51</sup> While modest in the startup costs it imposes on employers, the Hazard Communication standard has the potential to alter management treatment of suspect carcinogens over the long term. In the short term, however, the Standard's effectiveness will be limited by the poor quality of the MSDS and employer training programs currently in place.<sup>52</sup>

### ***The Air Contaminants Standard***

A dramatic departure from substance-specific rulemaking, OSHA's 1989 Air Contaminants Standard<sup>53</sup> imposed permissible exposure limits (PELs) on 164 substances not previously regulated and lowered the PELs for an additional 212 substances that had been regulated under the start-up provisions of the original 1970 Occupational Safety and Health Act. Hailed as the centerpiece of a new approach to standard setting, the Air Contaminants Standard has also been severely criticized for the procedure used in selecting chemicals and for its choice of exposure limits.

The Air Contaminants Standard is explicitly based upon the Threshold Limit Values (TLVs) of the American Conference of Governmental Industrial Hygienists (ACGIH), a private non-governmental organization, whereas the 1970 OSH Act designates NIOSH as the primary source for recommended standards. The TLVs and the process by which they are

**TABLE 1—Number of Substances Classified as Confirmed or Potential Human Carcinogens by Five Scientific Organizations, and Number of Classified as Carcinogens by OSHA's Four Carcinogen Policies**

| Total Classified               | NIOSH<br>126 | ACGIH<br>49 | NTP<br>162 | EPA<br>181 | IARC<br>376 |
|--------------------------------|--------------|-------------|------------|------------|-------------|
| Generic Carcinogen Policy      | 126          | 49          | 162        | 181        | 376         |
| Substance-Specific Regulations | 22           | 16          | 19         | 18         | 20          |
| Hazard Communication Standard  | 126          | 49          | 162        | 181        | 376         |
| Air Contaminants Standard      | 11           | 9           | 6          | 8          | 9           |

**TABLE 2—Alternative Risk Management Strategies for Occupational Carcinogens**

|                                | Permissible Exposure Limit | Labeling and Worker Training | Exposure and Medical Monitoring |
|--------------------------------|----------------------------|------------------------------|---------------------------------|
| Generic Carcinogen Policy      | stringent                  | yes                          | yes                             |
| Substance-Specific Regulations | stringent                  | yes                          | yes                             |
| Hazard Communication Standard  | none                       | yes                          | no                              |
| Air Contaminants Standard      | weak                       | no                           | no                              |

established have come under increased scrutiny, partly as a result of OSHA's reliance upon them. Analysis of the minutes of the TLV committee and other documents has uncovered a major but unacknowledged role played by the producers of the chemicals.<sup>54</sup> An analysis of the epidemiological studies referenced as part of the documentation for the TLVs found that the TLVs were generally established at levels commonly reported as prevalent in industry rather than at levels below which no significant adverse health effects were reported.<sup>55</sup> The TLV-based PELs for 98 substances in the Air Contaminants Standard were considered insufficiently protective by NIOSH.<sup>56</sup> Both industry and labor representatives asserted that the PELs mandated by the Air Contaminants Standard may create some problems of compliance for small firms but none for major producers.<sup>57</sup>

The treatment of occupational carcinogens under the Air Contaminants Standard is inconsistent and incomplete. While 78 of the substances covered by the Standard are considered confirmed or potential human carcinogens by NIOSH, ACGIH, and/or NTP, only 11 are regulated under the standard based on cancer risks. The others are regulated based on noncarcinogenic effects. Excluded alto-

gether from the Air Contaminants Standard are 68 substances considered to be confirmed or potential human carcinogens by NIOSH, ACGIH, and/or NTP.<sup>58</sup>

The Air Contaminants Standard makes no consistent distinction between epidemiological and laboratory evidence in regulating substances as carcinogens. Of the 11 substances regulated as carcinogens, six had epidemiological evidence of cancer effects in workers while five had only laboratory evidence of cancer in animals. Of the 67 substances regulated based on noncarcinogenic effects alone, five were considered confirmed human carcinogens by NIOSH, ACGIH, and/or NTP based on epidemiological evidence. Of the 68 substances considered as confirmed or potential carcinogens by the three scientific bodies but excluded altogether from the standard, 11 had epidemiological evidence of cancer in humans.

The Air Contaminants Standard is also inconsistent in the stringency of the exposure limits placed on particular substances. Of the 11 substances designated as carcinogens, seven have PELs set equal to the TLV, three have PELs set lower than the TLV, and one has a PEL set higher than the TLV. OSHA computed the residual risk of cancer (maximum likelihood estimate) for workers ex-

posed to seven of these 11 substances at the new PELs. These residual cancer risks ranged from 0.3 cases per 1,000 workers to 40 per 1,000, with a median of 3.7 and a mean of 10.1. By way of comparison, the maximum likelihood estimates of the residual risk under the substance-specific standards promulgated during the 1980s ranged from 0.0006 per 1,000 for formaldehyde<sup>59</sup> to 1.7 per 1,000 for ethylene oxide,<sup>60</sup> 6.7 per 1,000 for asbestos,<sup>61</sup> and up to 9.5 per 1,000 for benzene.<sup>62</sup>

## Conclusion

OSHA's official cancer policy, the 1980 Generic Carcinogen Policy, is comprehensive in the universe of substances covered and stringent in the exposure limitations proposed, but languishes in ignominious neglect. The substance-specific regulations present a politically risk-averse contrast. Eschewing chemicals lacking epidemiological evidence of cancer in humans, they devote enormous resources to documenting significant risk and economic feasibility and impose permissible exposure limits on a very few substances. The 1983 Hazard Communication Standard rivals the Generic Carcinogen Policy in the scope of substances covered but establishes a quite different and less direct form of incentives for management to reduce workplace exposures. The 1989 Air Contaminants Standard rivals the Generic Carcinogen Policy in imposing permissible exposure limits for hundreds of toxic chemicals, but abandons internal consistency with respect to the stringency of the particular limits imposed and external consistency with the recommendations from scientific bodies.

The inconsistencies between OSHA's four carcinogen policies are highlighted on Tables 1 and 2. Table 1 presents the number of substances commonly found in the US workplace environment that are designated as confirmed or potential human carcinogens by five scientific bodies, plus the number of substances on each of these five lists that is covered by each of OSHA's four carcinogen policies.<sup>53</sup> The breadth of the Generic Carcinogen Policy and the Hazard Communication Standard is illustrated by their coverage of all substances listed by the five scientific bodies. In stark contrast, OSHA's substance-specific regulations and the Air Contaminants Standard cover only a very small fraction of the listed carcinogens. Most remarkable, perhaps, is the contrast between cancer designations in the Air Contaminants Standard and the

designations by NIOSH, the organization to which OSHA officially responds. NIOSH considers 76 of the substances covered by the Air Contaminants Standard to be potential human carcinogens, but OSHA only set 11 permissible exposure limits based on avoidance of cancer risk. The Standard excludes altogether 26 substances considered occupational carcinogens by NIOSH.

Table 2 describes that risk management strategy embodied in each of OSHA's four carcinogen policies. Two of the policies impose stringent permissible exposure limits, one imposes weak limits, and one imposes none. The encouragement of worker self-help initiatives through container labeling and employee training is comprehensive in three policies but absent from the Air Contaminants Standard. Only the Generic Carcinogen Policy and the substance-specific regulations contain provisions for exposure monitoring and medical surveillance.

Progress in society's efforts to reduce the incidence of work-related cancer will only come as part of a general reform of occupational health policy at OSHA. On the political front, the shortest odds are for continued stalemate and perpetuation of the status quo. Among outside observers of OSHA's policies, however, a consensus may be growing as to a way to save generic rulemaking.<sup>13,64</sup> This would involve a major compromise to give up the illusion of imposing exposure limits at the lowest feasible level, in exchange for the ability to rely upon animal evidence of carcinogenicity and hence accelerate the pace of standard-setting. Briefly, OSHA could focus on a wide range of substances for which the available evidence might not survive a "significant risk" judicial review but which could pass a less stringent "material impairment of health" review. For these substances, OSHA could impose moderate "best available technology" standards modeled upon EPA experiences with the Clean Water Act.<sup>65</sup> More stringent (lowest feasible) standards would be reserved for the much smaller class of substances that could withstand a "significant risk" review.

This proposal is certain to elicit criticism both from those dissatisfied with the outcome of technology-based standards for environmental regulation and from those attached to the symbolic value of the "lowest feasible" regulatory approach. Technology-based standards provide no guarantee that the residual risks are acceptably low and may create disincentives for industry to develop new control meth-

ods that might then be mandated as the "best available."<sup>66</sup> Nevertheless, the technology-based approach retains its pragmatic appeal and has been incorporated for the control of hazardous air pollutants in the revised Clean Air Act.<sup>67</sup> As for critics insistent on OSHA's lowest feasible level strategy, the fate of OSHA's Generic Carcinogen Policy should serve as a note of caution. The real world of power and politics seems to offer stringent limits and narrow scope, as in the substance-specific standards, or broad scope and weak limits, as in the Air Contaminants Standard. What is needed is a mutually consistent and supportive set of standards that deal with each different aspect of the overall risk management strategy. When combined with the Hazard Communication Standard and the proposed generic exposure monitoring and medical surveillance standards,<sup>68,69</sup> an appropriately revised exposure limit policy could provide the foundations for an effective generic approach to controlling occupational carcinogens. □

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## Health Care Received by American Children: NCHS Report

The vast majority (83 percent) of American children are covered by health insurance, have a regular source of health care (88 percent), and visited a doctor in the past year for routine health care (64 percent) according to a recent report issued by the National Center for Health Statistics. The report cites new evidence, however, that America's minority and poor children receive less care, including preventive services.

The report, *Health Insurance and Medical Care: Health of Our Nation's Children, United States, 1988*, is derived from data from the 1988 National Health Interview Survey on Child Health, conducted by NCHS. Questions on health insurance and sources of medical care were asked for for all 17,110 children in a nationally representative sample of children 17 years of age and under.

The survey shows that Black newborns and infants were 2 to 3 times more likely to have lacked a routine visit for a

check-up or any immunization during the first year of life than were White newborns and infants. Hispanic children were twice as likely to have no health insurance coverage, either public or private, as non-Hispanics.

Most children with a regular source of health care had private care; however, 16 percent of those children (8.7 million) received health care from hospital clinics, emergency rooms, walk-in or emergency centers or other clinics. Clinics were the source of care for 47 percent of Black infants, compared to 16 percent of White infants. For Hispanic infants, almost half received health care in clinics.

The report, *Health Insurance and Medical Care: Health of Our Nation's Children, United States, 1988* is available from the National Center for Health Statistics, Centers for Disease Control, US Public Health Service, 6525 Belcrest Road, Hyattsville, MD 20782; (301) 436-8500.