Asbestos Criteria Document Highlights

ABSTRACT. Environmental research indicates that exposure to asbestos may be a significant hazard beyond that long recognized by the manufacturing and processing industry. Recent data supports the concern of environmental health specialists that asbestos may adversely affect workers in construction, maintenance, and other occupations far removed from asbestos manufacturing. Criteria standards calling for engineering controls and substitution of less hazardous materials should reduce the threat of pulmonary disease attributable to exposure to asbestos.

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Editor's note: The following was presented by Dr. Selikoff as a talk during the Society's Professional Development Conference held June 25-27, 1973, in Dallas, Texas.

When three years ago we heard that NIOSH and later the Department of Labor had decided to review asbestos first in the series of criteria documents that was to be prepared and to set the standards that were to be promulgated, this decision was accepted with mixed relief and apprehension. This was a rather urgent problem disease. Industry was somewhat in a turmoil since it was being asked to undertake expensive and extensive revisions and charges.

Labor was very resentful over what had occurred in terms of disease among workmen, and government was obviously very much on the defensive.

On the other hand, there was a great deal of apprehension because the problem was going to be approached from a very limited data base.

PLAINTIFF'S EXHIBIT

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Table 1

Expected* and observed number of deaths among 625 New York-New Jersey asbestos insulation workers, Jan. 1, 1943-Dec. 31, 1971, twenty or more years after onset of first exposure to asbestos.

	1943-1947		1948-1952		1953-1957		1958-1962		1963-1971		Total	
	Exp.	Observ.	Exp.	Observ.	Exp.	Observ.	Exp.	Observ.	Exp.	Observ.	Exp.	Observ.
Total Cancer: all sites	5.7	13	8.1	17	13.0	26	9.7	39	15.7	94	52.2	189
Lung cancer	0.8	5	1.4	8	2.0	12	2.4	17	4.8	42	11.4	84
Pleural mesothelioma	**	1	**	0	**	1	**	1	**	5	**	8
Peritoneal mesothelioma	**	0	**	1	**	2	**	1	**	20	**	24
Cancer of stomach, colon, rectum	2.0	4	2.5	4	2.6	7	2.3	4	3.1	12	12.5	41
Cancer all other sites	2.9	3	4.2	4	5.4	4	5.0	6	7.8	15	28.3	32
Asbestosis	**	0	**	1	**	4	**	7	**	21	**	33
All other causes	34.0	15	42.7	36	43.6	55	44.8	42	69.3	53	236.3	201
Total all causes	39.7	28	50.8	54	56.6	85	54.4	88	85.0	168	288.5	423
Person years of observation:	1,912.0		2,478.0		2,336.5		2,011.0		2,520.0		11,257.5	

532 members were on the Union's rolls on Jan. 1, 1943. Seven died before reaching 20 years from first employment. All others entered these calculations after reaching the 20-year-from-first-exposure point.

*Expected deaths are based upon death rate data reported annually by the U.S. National Office of Vital Statistics. Rates for 1968-1971 were extrapolated from age-specific rates for 1961-1967.

**U.S. death rates not available, but these are rare causes of death in the general population.

Table 2

Expected* and observed deaths among 933**
amosite asbestos factory workers first
employed 1941-1945, and observed to Dec. 31, 1971.

	Before 1952		1952-1961		1962-1971		Total, 1941-1971	
	Expected	Observed	Expected	Observed	Expected	Observed	Expected	Observed
Total deaths	69.98	88	108.27	146	121.24	250	299.49	484
Total cancer: all sites	9.81	15	18.72	44	21.63	84	50.16	143
Lung cancer	1.49	3	3.71	23	6.21	47	11.41	73
Pleural mesothelioma	***	1	***	0	***	2	***	3
Peritoneal mesothelioma	***	0	***	0	***	4	***	4
Cancer of stomach	1.45	3	1.84	4	1.29	4	4.58	11
Cancer of colon, rectum	1.56	2	2.61	5	2.88	8	7.05	15
Cancer of esophagus	0.27	0	0.45	0	0.51	0	1.23	0
All other cancers	5.04	6	10.11	12	10.74	19	25.89	37
Asbestosis	***	3	***	7	***	17	***	27
All other causes	60.17	70	89.55	95	99.61	149	249.33	314

*Expected rates are based upon age-specific death rate data of U.S. National Office of Vital Statistics from 1949-1967. Rates were extrapolated 1941-1948 from rates for 1949-1955 and for 1968-1971 from rates for 1961-1967.

**933 men were employed. In 5 cases, ages were not known and these men have been excluded from these calculations. 877 men were traced to death or to Dec. 31, 1971. 51 men were partially traced and remain in the calculations until being lost to observation.

***U.S. death rates are not available, but these are rare causes of death in the general population.

(continued on next page)

Little Scientific Research Into Problem

The first cases of asbestos disease in our country were reported in 1930, and soon after a very good Public Health Service study under Dr. Dreesen and his colleagues, was undertaken. But from that point on, from the early 30's to the early 60's, there was virtually a total absence of scientific research into this problem. Therefore when in 1969, 70, and 71, decisions were to be made, we didn't have a great deal on which to rely.

Secondly, data that had been collected during the 1960's suggested that this was a very complex problem. We should not have been surprised at this, because this complexity had, as we reviewed the situation, existed almost from its inception.

The first case of asbestosis, i.e., lung scarring as a result of inhalation of asbestos dust, was reported in 1924 by Dr. Cooke of Leeds, after he had done a post mortem on a young woman who had very extensive scarring throughout her lungs. He very astutely noted that she had worked in an asbestos textile factory. However, what he did not know and could not answer was how her exposure in that factory had resulted in the disease. What he could not answer was how much of the dust that she had inhaled

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Table 3

Expected and observed deaths of lung cancer among 876 amosite asbestos factory workers, first employed 1941-1945, and observed to Dec. 31, 1971.* Distribution by duration of employment.

Duration of employment	Number of Men	Person-years of observation	Deaths of lung cancer		
			Exp.**	Observ.	Ratio
< 3 months	256	5,869	3.55	13	3.66
3-11 months	294	6,158	3.58	15	4.19
1+ years	326	6,912	4.09	45	11.00
Total	876	18,939	11.22	73	6.51

*This table excludes 57 men. 10 died during first year of employment, 39 could not be traced after the first year, 7 had prior occupational exposure to asbestos and 1 had employment of uncertain duration. 17 men of the 876 were partially traced and remained in the calculations only until lost to observation.

**Expected rates are based upon age-specific rate data of U.S. National Office of Vital Statistics, 1949-1967. Rates were extrapolated 1941-1948 from rates for 1949-1955 and for 1968-1971 from rates for 1961-1967.

in the 20 years of her employment was necessary to cause the fibrosis.

She had worked 20 years and had inhaled a great deal of dust, but how much of that dust was "wasted" in terms of production of disease, was not known. He did not know nor do we today, whether one day, one week, one month, one year, or three years of that dust was required for her to have the scarring she suffered, and to subsequently die.

In the years after Dr. Cooke's report we learned a good deal. The most important thing we learned was that whatever asbestos does, takes a long time to become clinically evident. For example, 1,000 asbestos insulation workers were examined by us in the New York metropolitan area; of the 725 with less than 20 years from onset of exposure, most had normal X-rays. Only a minority had abnormal X-rays. When they were abnormal they tended to be only minimally so. On the other hand, once the 20-year point had passed, most had abnormal X-rays; and when they were abnormal they frequently were extensively so.

The next lesson we learned was that "years of exposure" was not necessarily synonymous with "years from onset of exposure." In other words, there was an important variable rarely included in the usual analysis of dose-disease response relationships—the variable of *residence time* of the dust in the lungs.

Cases have been seen of two, four, six weeks of exposure—probably intensive exposure—30 years ago, with extensive current fibrosis. The explanation is that the individual had six weeks of exposure.

The lungs which contained the dust inhaled in those six weeks, had since had 30 years of exposure. Thus, residence time had to be added to the complex biological equation we were to formulate.

We also found in these 30 years that, in addition to the lung itself being involved, not infrequently the covering of the lung, the pleura, also was frequently involved, tnat more than one tissue could be affected. This also followed the 20-year rule. For example, of the 725 with less than 20 years from onset of exposure, most had a normal pleura on X-ray. On the other hand, once the 20-year point had passed, fibrosis and/or calcification were common.

This has special significance in that whatever we have seen to this point, is the result of exposure from 1920, 1930, 1940, or 1950. In 1930, the United States used around 120,000 tons of asbestos, so what we are seeing now is the result of such levels of use. We are now using about 700,000 tons of asbestos each year. Disease associated with current use of asbestos will not be seen until the year 2000.

Nature Was Jogging Our Elbow

While we were learning these things, nature was jogging our elbow. In 1935, Dr. Kenneth Lynch, at that time Professor of Pathology at the Medical Uni-

versity of South Carolina (recently Chancellor there) reported a very unusual case of a man who had asbestosis and lung cancer. One may wonder what was so unusual about this case, that the editor of the *American Journal of Cancer* accepted it for publication. It may be hard for us to now appreciate that in 1935 lung cancer was a rather rare disease. The reason is that it, too, follows a 20-year rule. Youngsters begin smoking cigarettes at the age of 18, 12, 14, 9, 20. They do not die of lung cancer at 25, 30, 21. They die at 58, 63, 49.

It is therefore significant that, in 1935, there were not many people in our country who had begun smoking cigarettes in 1910, for example. We did not become a nation of cigarette smokers until after the First World War. Therefore, a case in 1935 which combined two diseases, asbestosis and lung cancer, each with a long waiting period, would be very unusual. However, the purists among us, bio-statisticians, epidemiologists, careful people, noted that what Dr. Lynch had described, and others too, couldn't be accepted as necessarily related, since we could not rule out a chance rather than an etiological association. The truth is that the statisticians were right. Their reticence was perfectly valid.

The same criticism was equally valid in 1954 when a second disease, mesothelioma, a cancer of the lining of the chest (the pleura) was reported by Dr. Weiss in Germany in a man who also had asbestosis. This was a very unhappy finding. First of all, to that point mesothelioma was very rare. How rare, we don't know. It was so rare that it was not separately coded in the International Classification of Causes of Death.

Therefore, no valid statistics are available. The best evidence we have is that it was something around one out of every 10,000 deaths.

Among people with asbestos exposure, it soon after 1954 began to be reported frequently. When it was, it was disheartening since it was invariably fatal.

When the lining of the abdomen becomes involved, as was soon found in asbestos workers (mesothelioma of the peritoneum), it too is diffuse, and it also is invariably fatal.

We didn't know in the 1950's how much of a

Table 4

Expected* and observed deaths among
17,800 asbestos insulation workers
in the United States, January 1, 1967-December 31, 1971

	Total		Distribution by duration from onset of exposure			
			Less than 20 years		20 years and more	
	Expected	Observed	Expected	Observed	Expected	Observed
Total deaths	805.63	1,092	178.94	211	626.69	881
Cancer: all sites	144.09	459	26.31	51	117.78	408
Lung cancer	44.42	213	7.03	22	37.39	191
Pleural mesothelioma	**	26	**	2	**	24
Peritoneal mesothelioma	**	51	**	3	**	48
Cancer of stomach	6.62	16	0.97	1	5.65	15
Cancer of colon, rectum	17.51	26	2.51	3	15.00	23
Cancer of esophagus	3.21	13	0.44	1	2.77	12
All other cancers	72.33	114	15.36	19	56.97	95
Asbestosis	**	78	**	5	**	73
All other causes	661.54	555	152.63	155	508.91	400
Number of men	17,800		12,681		5,119	
Person-years of observation	86,300		62,673		23,627	

*Expected deaths are based upon age specific death rate data of the U.S. National Office of Vital Statistics. Rates for 1968-1971 were extrapolated from rates for 1961-1967.

**U.S. death rates not available, but these are rare causes of death in the general population.

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Table 5

Deaths of lung cancer and pleural mesothelioma among 17,800 asbestos insulation workers in the U.S. and Canada, Jan. 1, 1967-Dec. 31, 1971: relation to elapsed period from onset of work exposure.

		Lung cancer		Pleural Mesothelioma
Years from onset	Expected deaths*	Observed deaths	Ratio	Observed deaths
< 10	0.48	0	--	0
10-14	1.69	4	2.4	0
15-19	4.86	18	3.7	2
20-24	7.55	25	3.3	4
25-29	8.50	41	4.8	7
30-34	6.24	44	7.1	4
35-39	3.53	23	6.5	1
40-44	4.04	24	5.9	3
45-49	3.72	17	4.6	4
50+	3.81	17	4.5	1
Total	44.42	213	4.8	26

*Expected deaths are based upon age specific death rate data of the U.S. National Office of Vital Statistics. Rates for 1968-1971 were extrapolated from data for 1961-1967.

problem these cancers would turn out to be. The matter was of some importance because until this point, the question was only whether our task was to prevent asbestosis, (lung scarring). Now it was whether it was to include something more, cancer. There was, and therefore our precautions would have to be related to all.

In the last several years, a number of studies have been done to bring together data on this aspect of the question. In one, 632 members of the Asbestos Workers Union in 1943 in the New York metropolitan area were studied. Age, year and sex, specific rates indicated that by the end of 1962 there should have been 203 deaths among them. There were 255. Fifty men died in this one union who were not expected to die.

Looking at the death by cause, six or seven deaths of cancer of the lung and pleura were expected. There actually were 45. This obviously was where the major portion of the excess deaths were. Dr. Lynch was right in 1935, with his one case and with keen sense. Interestingly, there should have been nine or ten deaths of cancer of the stomach, colon, rectum and esophagus. There were 29. Individuals who inhale dust also ingest it. There were, as expected, 12 deaths of scarred lungs.

Observation has been maintained of the survivors in this group, to the end of 1971 and the resulting data may be of interest. Where there should have been, from 1963 to 1971, another 85 deaths, 168 occurred. There should have been five deaths or so of lung cancer. There were 42. There should have been no deaths of mesothelioma. There were 25. There were increases in cancer of the stomach, colon, and rectum and excess deaths of asbestosis.

Altogether, from 1943 through 1971, 430 of the 632 men died, giving us a good idea of what happened to asbestos workers. One out of every five deaths was due to lung cancer, one out of every 15 due to mesothelioma, one out of every 10 or so due to gastro-intestinal cancer, and almost one of 15 due to scarred lungs.

How Do We Know It Was Due to Asbestos?

The question has properly been raised, how do we know it was due to asbestos rather than other materials used in the insulation industry, such as fibrous glass, cork, rockwool, calcium silicate, diatomaceous

earth. To study this we studied workers in a factory making insulation, men who made insulation used in construction industry, in refineries, chemical plants, shipyards, etc. In 1941, a factory in Paterson, New Jersey, was opened to manufacture insulation material of amosite asbestos, largely for the U.S. Navy. Between 1941 and 1945, 933 men worked there, some for as little as one day, some until the factory closed in 1954.

We have followed these 933 people through December 31st, 1971. Given their ages at the time they began work, 300 were expected to die. 484 did. Where there should have been 11 deaths of lung cancer, 73 occurred. There were expected excess deaths of mesothelioma, gastro-intestinal cancer, and asbestosis. These data indicated that it was the asbestos insulation materials and not other conditions in the construction industry.

The problems next raised were whether this was a local condition, something related to the situation in New York, and whether it was limited to very long work. We studied these questions in two ways. The second concerning how much dust causes disease and how much is "wasted exposure" was studied by analyzing the experience of the men in the factory by duration of employment. About one third worked for less than three months, one third for three to 11 months and one third for more than a year. We found that those who worked for more than a year had the greatest risk of death of lung cancer. But even with less than three months, a very significant increase in observed over-expected deaths of lung cancer was observed. Some of the exposure after three months was in that sense "wasted."

The second question was answered by seeing what happened to asbestos insulation workers throughout the United States. On January 1, 1967, there were 17,800 members of the Insulation Workers Union in the United States and Canada. We made a list of every man, tracing them through December 31, 1971. We didn't expect to find very much abnormal, since for the first five years, almost any employed group has a better expected health and mortality experience. The reason is that our comparison is with the general population, which contains many sick people, people in hospitals, people chronically ill. An employed group is apparently well enough to go to work, and therefore for five years, we expect them to not have as many deaths as the general population. We had an unwelcome surprise, however.

Given the ages of these men in 1967, there should have been 806 deaths. There were almost 1,100; lung cancer, 44 expected, 213 observed, no deaths of mesothelioma were expected, and 77 occurred. There was the same two to three times increase of gastro-intestinal cancer, and 78 deaths of asbestosis.

Therefore, it was evident that at least two problems have to be considered in terms of prevention of disease due to asbestos exposure, lung scarring and cancer. We also observed that, as asbestosis, the various forms of cancer generally do not occur until after the 20-year point has passed.

One would think we had enough problems as we approached the question of what to do about occupational exposure to asbestos. However, in the 1960's an additional question arose. Until then, we had as our scientific resource for the measurment of exposure, the microscope. How many fibers are present? However, fibers are not solid units. They are composed of numerous fibrils banded together to make the fiber. If, instead of the optical microscope, you were to use an electron microscope, you would see fibrils of about 300 to 350 Angstroms in diameter. These cannot be seen with the optical microscope; they are far below the limits of its resolution. Therefore, in measuring the number of particles, many more are seen with the electron microscope than if only the optical microscope is used.

It was hoped that the optical microscope would at least provide a useful index. It was soon found that this was not so. For example, when asbestos blankets were fabricated, for example, aboard ship, it was found that only 29% were more than five microns in length. On the other hand, when cutting silicate block, only 3.5% were five microns in length and 96.5% were smaller. In other work only ½% were more than five microns, 99.6% were smaller than that. In other words the standard is questionable because in different asbestos uses we were looking at a *variable proportion* that can be seen with the optical microscope.

Additional Difficulties

In recent years additional difficulties have been placed upon us. To return to mesothelioma, you will remember how rare it has been in the past, about one in 10,000 deaths. One can imagine the consternation, then, when in 1960 J. C. Wagner reported 47 cases of mesothelioma, all in one part of South Africa, in five years, 1956 to 1960. Most were in a part of South Africa in which there were many asbestos mines and mills. Dr. Wagner visited the relatives of these people and inquired about possible asbestos exposure. He found that in most cases there had been 25, 30 years before opportunity for asbestos contact, often not by working with the material but by limited contact in environmental or family circumstances.

With this knowledge Muriel L. Newhouse, a very capable epidemologist at the London School of Hygiene, studied the 76 cases of mesothelioma in the files of the London Hospital. She found that of the 76 cases, 31 had worked with asbestos. More important, of the 45 who had not worked with asbestos, nine had simply lived in the household of an asbestos worker and 11 had lived within a half mile of one of the asbestos plants in London.

Jan Lieben, at that time with the Pennsylvania State Department of Health, studied the 42 cases of mesothelioma in their files. Twenty had worked with asbestos. Of the 22 who had not, three had simply lived in the household of an asbestos worker and eight within a half mile of one of the asbestos plants in Pennsylvania.

These studies raised for the first time the question whether intimate and immediate occupational exposure to asbestos was required for the production of asbestos disease or whether others, as those with indirect occupational exposure, might also have this risk. This new question, not unimportant, has now been placed before us. Incidentally, it is not considered in the asbestos standards that have been set by the Department of Labor.

How important the problem is may be gauged from the fact that in the last several years, over 50 cases of mesothelioma have been found in one shipyard in Great Britain, at the Devenport Dock Yards, and have been reported by Dr. Peter Harries, the Medical Officer in charge. In shipyard after shipyard, this is now being seen. For example, 80 cases of mesothelioma were recently reported from Scotland; all were in the seaport cities. Whitwell and Rawcliffe two years reported 28 cases of mesothelioma, all in shipyard workers; only four worked directly with asbestos. They stated, " . . . it seems the exact nature of their work was much less important than the fact that they all worked in shipyards."

One can imagine asbestos workers, electricians, plumbers, steam-fitters, boilermakers, all working cheek by jowel. Perhaps the only thing in the construction industry and shipyards that does not obey jurisdictional craft lines, is the asbestos fiber. In the construction industry this is an immediate and urgent problem, as when asbestos fireproofing is sprayed on steel.

Had Identified Major Problems

To recapitulate, the situation in 1971 was as follows: We had identified the major problems. We had a disease with a long latent period. In many cases there was a great deal of wasted exposure, but we didn't know how much. We knew that resident time in the lung was very important and therefore peak exposures had to be controlled.

We knew that more than one tissue was potentially being affected.

We knew that perhaps 80% of the excess deaths were being caused by cancer and not by asbestosis. We also knew that various sizes of fibers, small and large, were present. And we knew also that many advances in engineering and procedural techniques had already been identified and that many more could be anticipated.

At that point NIOSH and the Department of Labor wrestled with the problem and wrote first a criteria document and later wrote standards.

They made a number of decisions. First of all, they decided to ignore cancer because while they had some hint of what it might take to prevent lung scarring, they didn't know how little exposure there would have to be to prevent cancer. Many cases of cancer, especially mesothelioma, were found in the absences of scarring. Since they didn't know how to evaluate that, they apparently decided to at least judge what they did know.

Let's see what we need to do to prevent scarring even though this is only 20% of the problem.

They decided to keep their fingers crossed as a means of protection against the problem of resident time in the lung. They recognized that effective control procedures have been developed but rather than make them mandatory, which would be inconvenient, they decided to simply mention them in the document, requiring them used only if the dust counts were too high. Otherwise what we already knew in terms of engineering was not to be required. For example, unless the dust counts were going to be above a legal limit, one needn't worry about bagging the waste, or using respirators or dust collectors. These were only mandatory if the dust counts were too high, if dust counts were above a specific level. Therefore, the engineering advances that have been made were kept in the drawer in reserve, as it were.

Thus, instead of a sharp reliance on demonstrably effective engineering practices and procedures, a number standard was elected.

It may be interesting for you to review how we came to get a number standard and the number standard we have. A basic difficulty in establishing a number standard (or a dose-disease relationship) is that the disease we now see was initiated 30 years ago at a time when few dust counts were done. We have inadequate data to relate what we are now seeing in terms of disease and death with exposures in 1930 or 1940. Few dust counts were done. Secondly, when they were done, our present techniques were not used. No filters were then available, for example. Instead of counting fibers, all particles were counted, in million particles per cubic foot. It is very difficult to convert particles to fibers, for many technical reasons. There are two ways of approaching this dilemma. One is to seek dust counts that were done 30 years ago. Some good counts were done, especially those by Fleischer in 1944-45 for the Navy. Another is to make dust counts today, and to judge how relevant conditions are today, to what might have existed 30 years ago.

This was the attack used by Cooper in San Francisco, and by our laboratories. We find that using the latter techniques the time-weighted (eight-hour) average was between five to ten fibers per cc. Five fibers per milliliter is five million fibers in a cubic meter of air, those longer than five microns. Smaller fibers may be 100 to 1,000 times as numerous. A

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worker inhales four to eight cubic meters of air in an eight-hour day. Therefore he will respire some 40 million fibers longer than five microns if the atmosphere contains five fibers per cc. How many fibers are retained is not known.

Standard Came Into Force June 7, 1972

The standard came into force on June 7, 1972. It required that by December 6 every asbestos-using operation had to do at least one dust count. We waited until December 7, the day after the six-month period, and then a survey was done of a large number of asbestos insulation workers in this country. Each was asked about dust counts that he personally had seen. We had over 5,000 replies.

Of 5,000 respondents, 4,956 had not seen a dust count done. Only 171 personally saw one or more dust counts.

For practical purposes, despite a serious situation, dust count surveillance was not undertaken in this country. We also asked many other things.

We asked specific questions, for example, about respirators. Almost one quarter of the men never had them provided by the employer and one quarter had only occasionally had them available. We asked about specific procedures now known; cement in plastic bags, 10% of the time, power table saws, 10% of the time, vacuuming of waste for disposal, 10% of the time, drop cloths, trivial number of times, portable exhaust for confined spaces, trivial number of times. To prevent the dust from going home to the family we asked whether facilities at the plant for clothing changes were available. They were available all of the time in only 25% of instances. In almost 40% such clothing changes were never available.

So, for practical purposes, the criteria document has had very little effect on the situation.

In conclusion may I express the hope that we will not long remain in the difficult situation in which we now find ourselves. The Department of Labor has recently announced that it will reopen the question of the asbestos standards. This is all to the good. Surely the problem is a solvable one. Industry is much too competent, labor is much too concerned, science has too much reliable and pertinent data and government is far too responsible for us to admit defeat.

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