



The Bush Regulatory Record

A Pattern of Failure



This analysis was written by Robert Shull, Senior Regulatory Policy Analyst, and Genevieve Smith, Policy Analyst. It also incorporates material written by former OMB Watch analysts Reece Rushing and Melissa Brennan.

OMB Watch is a nonpartisan, nonprofit research and advocacy center which promotes an open, accountable government responsive to community needs. Founded in 1983, OMB Watch at first focused on lifting the veil of secrecy from the White House Office of Management and Budget. Since then, OMB Watch has grown to address in depth the issues we originally covered in the context of monitoring the OMB. Our main issue areas are federal budget and tax policy, information and access, nonprofit advocacy rights, and regulatory policy.



*1742 Connecticut Avenue NW
Washington, D.C. 20009*

*(202) 234-8494
www.ombwatch.org*

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Executive Summary

Even though overwhelming majorities of the public believe that the government has an important role in protecting the public interest,¹ the Bush administration is continuing to shape regulatory policy in ways that are hostile to the public interest. This administration is failing to give the public the protections we deserve. It continues to abandon work on documented public health, safety, and environmental problems. Instead of identifying other priorities for serving the public, this administration is doing nothing. It cannot meet even short-term benchmarks for action, and it is allowing proposals for addressing long-identified needs to languish on its regulatory agenda. Finally, what little this administration has accomplished is not strong enough to meet the public's needs but, instead, is weakened at the behest of industry interests.

In this analysis, we looked at four agencies that are particularly important to the public interest: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the Occupational Safety and Health Administration (OSHA). We looked at the agencies' record from the last year, and we built on that analysis to get a comprehensive picture of the Bush administration's regulatory record to date.

The Last Year

We began by studying the December 2003 and June 2004 editions of the Unified Agenda, a semiannual publication in which the agencies declare their regulatory priorities, list timetables for accomplishing their plans, and announce the status of items from previously-published plans.

Shirking Responsibility

During the last year, the administration continued to abandon work on proposals to address long-identified public health, safety, and environmental needs. Since the Bush administration took office, the vast majority of items

1. See Louis Harris & Peter Harris Res. Grp., Inc., *Survey of the Attitudes of the American People on Highway and Auto Safety: Wave Five of a Periodic Tracking Survey* (June 2004), available on-line at <<http://www.saferoads.org/polls/harrispoll04.htm>> (hereinafter "Harris Survey").

withdrawn from the Unified Agenda by the four agencies studied in this analysis were items inherited from past administrations—some of which had been added to the agenda by the Reagan and Bush I administrations.

- EPA withdrew 25 agenda items in the last year, bringing the total withdrawn by this administration to 90. Most of the withdrawn items would have addressed Clean Air Act and Clean Water Act priorities.
- The FDA withdrew four more items from the agenda this year, bringing its total of withdrawn items to 62 (of which 52 were first proposed by the Clinton administration). Among these abandoned priorities was a proposal to create a tracking system notifying patients who receive contaminated blood products in the event of recalls.
- NHTSA withdrew 13 more items during the last year, bringing its total withdrawals during this administration up to 31, of which 23 were proposed by the Clinton administration, two were proposed by the Bush I administration, and two had been on the agenda since the Reagan administration.
- OSHA targeted two more items for removal in the last year, bringing its total number of withdrawals to 24 (of which three date back to the Reagan administration, while two date back to Bush I, and the remaining 19 were date back to the Clinton administration). One was a proposal to protect workers from exposure to tuberculosis.

Inaction

The administration justified abandoning those initiatives by arguing that it was shifting resources to other priorities. Nevertheless, the administration is failing to work on its own priorities. The administration failed to achieve most of its benchmarks for the last six months, and it

continued to allow proposed remedies for urgent public health, safety, and environmental problems to languish unaddressed on agency agendas.

- EPA failed to achieve 73 percent of the benchmarks it had scheduled for completion during the last six months. Meanwhile, three proposals for protecting drinking water languish on the agenda, two since 1999 while the third dates to at least the Bush I administration.
- The FDA failed to complete 70 percent of its projected benchmarks for the last six months. The agency also delayed its January 2004 promise to safeguard against mad cow disease by closing a loophole in the ban on ruminant-to-ruminant feeding.
- NHTSA failed to achieve 71 percent of its benchmarks in the last six months. Of the 85 items still on the NHTSA agenda when the Bush administration took office, 31 were abandoned while another 23 remain uncompleted.
- OSHA failed to advance 75 percent of its benchmarks slated for action in the last six months. Important workplace safeguards—including employer payment for required personal protective equipment and protections from workplace exposure to hexavalent chromium—linger, unfinished, on the agency's agenda.

Industry Interests Over the Public Interest

The Unified Agenda reveals that, when the administration is roused to issue final rules, those rules are generally weak, putting corporate special interests over the public interest.

- EPA completed only three economically significant items on its last two agendas, one of which was not even a rulemaking but represented only the perfection of a record that had been challenged on appeal,

whereas the other two have been challenged in court for insufficiently protecting the environment.

- The FDA likewise completed only three economically significant items, one of which will not be effective for several years while the other two are tilted in favor of regulated industry. One rule, which limits certain patent filings that can delay entry to the market of generic pharmaceuticals, still leaves uncompleted other important steps needed to stop major drug companies from blocking inexpensive generics.
- NHTSA completed a large number of agenda items in the last year, although only half of them were actually rules. The completed rules, which address auto safety concerns ranging from the prevention of post-crash fires to development of an early warning database of potential defects and safety hazards, are generally weak and shield the auto industry from accountability.
- OSHA's record of completed actions is essentially empty. Over the last year, OSHA can only point to three items that were completed, and one of those was not a new rule but only an analysis of a pre-existing rule's economic consequences. One of the two completed rules actually does not address a problem but instead sweeps one under the rug by eliminating data collection of musculoskeletal disorders. OSHA has yet to produce a single economically significant protection of workplace health or safety since the Bush administration took office.

The Four-Year Picture

The last year's record is only the latest evidence of a pattern of failure that has characterized the entirety of the Bush administration regulatory record. Although statistics alone do not suffice to provide a complete picture of this administration's failure to serve the public interest, a few numbers are dramatically illustrative.

This administration has abandoned work on scores of long-identified public health, safety, and environmental problems. The FDA and EPA alone have withdrawn 60 percent and 52 percent, respectively, of the agenda items carried over from previous administrations. Those not withdrawn altogether from the Unified Agenda languish, uncompleted. All four agencies have either withdrawn or failed to complete work on a majority (ranging from 53 percent on EPA's agenda to 86 percent on OSHA's) of the items that were already on the agency agendas when the Bush administration took office.

Moreover, the Bush administration has failed to identify the other priorities for serving the public interest that warrant abandoning or ignoring these identified needs. The Bush White House approved only 25 economically significant final rules from the four agencies. This meager output is in sharp contrast with the numbers approved by past administrations: 74 during the Bush I administration, 55 during the first term of the Clinton administration, and 51 during the second Clinton term. In EPA alone, that output has fallen from 40 during the first Clinton term to 11 during this administration.

A Pattern of Failure

This pattern of putting corporate interests over the public interest has real life consequences. Failure to protect the public—whether by safeguarding the quality of the air we breathe, the reliability of the vehicles we drive, the purity of the food we eat, or the safety of the places in which we work—has long-term implications for ourselves, our children, and the generations yet to come. When our government abdicates its responsibility to give us the protections we need, *people suffer*. This administration's pattern of failure leaves us with a dangerously weakened firewall of health, safety, and environmental protections.

Introduction: Continuing in the Wrong Direction

Even though overwhelming majorities of the public believe that the government has an important role in protecting the public interest, the Bush administration is continuing to shape regulatory policy in ways that are hostile to the public health, safety, civil rights, and environment. In this analysis, an update of OMB Watch's periodic retrospective reviews of the administration's regulatory record, we find that this administration's record this year is only the latest evidence of an overall pattern of failure.

Shirking Responsibility: During the last year, the administration continued to abandon work on proposals to address long-identified public health, safety, and environmental needs.

Inaction: The administration justified abandoning those initiatives by arguing that it was shifting resources to other priorities. Nevertheless, the administration is failing to work on its own priorities. The administration failed to achieve most of its benchmarks for the last six months, and it continued to allow proposed remedies for urgent public health, safety, and environmental problems to languish unaddressed on agency agendas.

Industry Interests Over the Public Interest: The administration is not giving the public the protections we deserve. It continues to produce few important protections of the public interest, and those it does produce are generally weak, putting corporate special interests over the public interest.

About this Analysis

This analysis is the fifth in a series of retrospective analyses of the Bush administration's regulatory record. Since 2002 we have been examining the Unified Agenda, a special feature in the *Federal Register* that, every six months, lists the regulatory priorities of the agencies, notes the stage of the process in

which the priority items are currently projected to be, and identifies which items are being removed from the agency agenda. We have been periodically using the publication of the agendas as an occasion for a retrospective review of regulatory priorities in a few representative agencies charged with serving the public health, safety, and environment.² Earlier this year we built upon that series of analyses in a major report (co-produced with the Center for American Progress on behalf of the coalition Citizens for Sensible Safeguards) that expands those analyses and makes the link between the Bush administration's choices in regulatory policy and their consequences for the public welfare. That report, *Special Interest Takeover: The Bush Administration and the Dismantling of Public Safeguards*, reveals that the Bush administration's assault on the network of regulatory protections is unprecedented in its breadth and depth.³

This analysis is based on the two editions of the Unified Agenda, published December 2003 and June 2004 and covering the period between May 22, 2003 and June 28, 2004.⁴ (Despite the actual season of the month in which an agenda is published, it is often referred to as either the "fall" or "spring" agenda of a given year.) As before, we continue to focus on a handful of agencies particularly important to the public interest: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the Occupational Safety and Health Administration (OSHA).

We are also continuing to publish tracking charts that show the cumulative progress, or lack thereof, of agency priorities throughout the agendas published during the Bush administration. We find that the tracking charts can be a useful tool for identifying priorities that are languishing, priorities being downgraded from final status (in which a final rule is expected

2. These prior analyses are available on the web at <www.ombwatch.org/regs/bushrecord>.

3. See OMB Watch & Ctr. for Amer. Prog., *Special Interest Takeover: The Bush Administration and the Dismantling of Public Safeguards* 69 text accompanying notes 42-43 (2004) (available on-line at <<http://www.ombwatch.org/bushrecord/takeover>>).

4. The December 2003 agenda was published in the *Federal Register* at 68 Fed. Reg. 72,401 (Dec. 22, 2003), and the June 2004 agenda was published at 69 *id.* 37,167 (June 28, 2004). Both are available on-line, along with past agendas reaching back to 1994, on the Government Printing Office website at <<http://www.gpoaccess.gov/UnifiedAgenda/index.html>>. A more user-friendly version from the General Services Administration's Regulatory Information Service Center is on-line at <<http://ciir.cs.umass.edu/ua/>>. Subsequent references to these and past agendas will simply refer to them by month and year or as the fall or spring agenda of a given year.

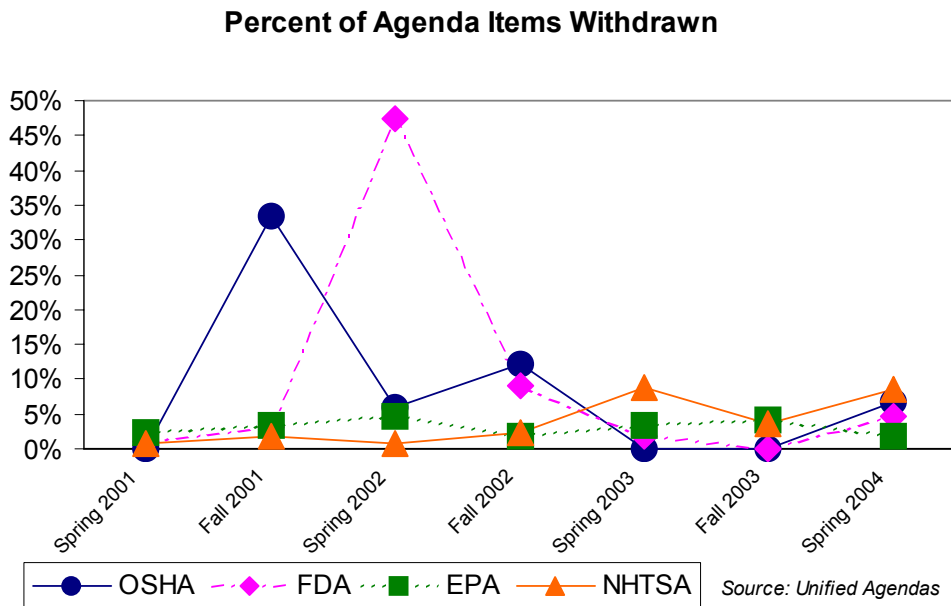
to be published within a definite time period) to something less than that such as long-term status (in which an agency believes a rulemaking will be an important step but cannot project any date for the issuance of one), and priorities being withdrawn en masse. Because the agencies report items withdrawn altogether in the same category as items that have been fully completed, we reclassified those withdrawn items on the tracking charts based on the agencies' statements in the explanatory text sections of the agendas.

Additionally, we are adding a new set of charts focusing just on these withdrawn items. We have compiled tables that set the agency's original statement of reasons for adding a priority to its agenda alongside its stated reason (if any) for withdrawing the priority. Both sets of charts are available on our website, along with electronic copies of this analysis, at <www.ombwatch.org/regs/patternoffailure>.

Findings

The Bush administration's record during the last year, as recorded in the fall 2003 and spring 2004 agendas of four agencies charged with serving the public interest, reflects that the administration is continuing its policy of hostility to protections of the public interest. Most of the major damage to regulatory policy was done earlier in the administration's term, but actions since reveal the same tendency to cave in to corporate special interests and the same indifference to the public health, safety, civil rights, and the environment. This administration's policy flies in the face of overwhelming public support for the government's important role in protecting the public welfare.⁵

5. See Harris Survey, *supra* note 1; see also OMB Watch, "New Poll Finds Overwhelming Majorities Favor Government Regulation for Health and Safety," available on-line at <<http://www.ombwatch.org/article/articleview/2283/1/4/>>. Nine out of ten respondents in that nationwide survey agreed that the government's role in ensuring the public safety in a range of areas (including food and other product safety, workplace safety, and highway and plane travel safety) is either very important or somewhat important.

Figure 1

Continuing to Shirk Responsibility

The administration abandoned most long-standing priorities in earlier years, but in the last year it continued to favor corporate special interests by dropping more items from the last two agendas.

Simply counting the number of withdrawn items does not necessarily quantify the extent to which work has been abandoned on long-identified priorities. Some of the agendas earlier in the Bush administration did show unusually large numbers of withdrawn items, as seen in Figure 1, and those large-scale withdrawals did tend to correspond with wholesale abandonment of crucial public welfare needs. Nevertheless, there are some withdrawn items that do not necessarily represent failures to serve the public:

- “Withdrawn” items occasionally reflect positive decisions, such as withdrawing a poorly-designed direct

final rule that elicits negative response⁶ or denying a petition for rulemaking submitted by industry interests.

- An item that would have addressed a specific instance of a larger problem is sometimes withdrawn as a distinct item because it is being folded into a consolidated effort to tackle the larger problem or because a separate rulemaking has fixed that specific issue in the course of fixing other aspects of the same problem.
- Some withdrawals record the formal removal from the agency agenda of an item for which outside events rather than agency choices have eliminated the need for agency action. Some examples:
 - the elimination of the need for the rulemaking because of changing practices and advances in technology,
 - congressional action undermining the agency's ability to regulate in a given area, and
 - a decision by an outside party who had filed a petition for rulemaking to withdraw that petition.

In cases such as these, the number of withdrawn items would reflect both decisions to abandon long-recognized needs and decisions that do not necessarily mean that an agency is failing the public. The problem, then, is not captured by the sheer *number* of withdrawn items; the problem is, instead, the nature of certain decisions to abandon work.

Looking behind the agendas reveals that the Bush administration continues to withdraw work on needed protections after the earlier mass

6. When an agency issues a direct final rule, it announces in the *Federal Register* that the rule will take effect as a final rule, without further notice, unless the agency receives adverse comments (in which case the agency will publish a formal withdrawal notice and return to the rulemaking process). A useful glossary of regulatory process terms is available on-line at <<http://www.reg-group.com/glossary.shtml>>.

withdrawals. Here are a few troubling items withdrawn from the last two editions of the Unified Agenda:

- Safety of the Blood Supply: The FDA abandoned a rule that would have required tracking systems to follow blood plasma products from the manufacturer to the recipient and would have made it possible to notify recipients in cases of recalls or potential contamination.
- Worker Exposure to Tuberculosis: OSHA dropped work on a rule to protect health care workers from exposure to TB, favoring instead voluntary standards that employers can choose to implement or ignore.
- Construction Runoff: Construction sites annually discharge an estimated 80 million tons of solids into U.S. waterways, but EPA abandoned (at the White House's urging) work on a proposal to require an 80 percent reduction in storm water discharges during and after construction.

As the charts of withdrawn rules on our website reveal, the four agencies have used several recurring excuses for abandoning these priorities—excuses that do not always withstand scrutiny.

- Other priorities: The most used excuse, usually in agendas with peak numbers of withdrawals, is that it is necessary to abandon work on pressing needs because the administration has identified other priorities that demand a reallocation of agency resources. As discussed below, however, those other priorities have not materialized. In fact, as one recent analysis suggests, this administration has proposed fewer major initiatives to replace withdrawn initiatives than prior administrations.⁷

7. See Amy Goldstein & Sarah Cohen, "Bush Forces a Shift in Regulatory Thrust: OSHA Made More Business-Friendly," *Washington Post*, Aug. 15, 2004, at A1 ("In the past 3 1/2 years, OSHA, the branch of the Labor Department in charge of workers' well-being, has eliminated nearly five times as many pending standards as it has completed. . . . Unlike his two predecessors, Bush has canceled more of the

- Voluntary options: Another favored reason, in particular for OSHA, is the administration's preference for voluntary guidelines. OSHA often cites the existence of industry-approved "best practices" or other guidelines that the agencies cannot enforce as a basis for eliminating work on a government regulation. The virtue of an enforceable rule is that it is applied across the board, and *everyone* can benefit from it. In other words, it is fair. In the case of a withdrawn rule that would have governed worker exposure to tuberculosis, OSHA cited voluntary guidelines from the CDC as a reason to abandon work on a fair rule, but statistics on TB rates show that, in the absence of a uniform rule, rates have not been declining everywhere at the same pace.⁸
- Waiting for more research: Several of NHTSA's rationales for withdrawing items argue that more research will give a more complete picture of the issue to be regulated. Curiously, NHTSA has used that argument to justify *withdrawing* an item rather than demote the item to long-term status. Although it can be hard to quarrel with the desire for more information, at some point it just becomes an excuse for delay. As a court recently chided another Department of Transportation agency, "Regulators by nature work under conditions of serious uncertainty, and regulation would be at an end if uncertainty alone were an excuse to ignore a congressional command"⁹
- Lack of comments: On several occasions, OSHA used the excuse that the rulemaking record has few public comments as a basis for abandoning work on a rule

unfinished regulatory work he inherited than he has completed He has also begun fewer new rules than either President Bill Clinton or President George H. W. Bush during the same period of their presidencies.").

8. See page 53 *infra*.

9. *Public Citizen v. Federal Motor Carrier Safety Admin.*, 374 F.3d 1209, 1221 (D.C. Cir. 2004).

rather than soliciting more comments. In some cases, however, that excuse appears arbitrarily applied: OSHA chose to complete a rule for commercial diving operators that received 13 total comments,¹⁰ but the agency abandoned work on safety conditions in shipyards that received equal or greater numbers of public comments.¹¹

Inaction: Continuing to Let Pressing Needs Go Unaddressed

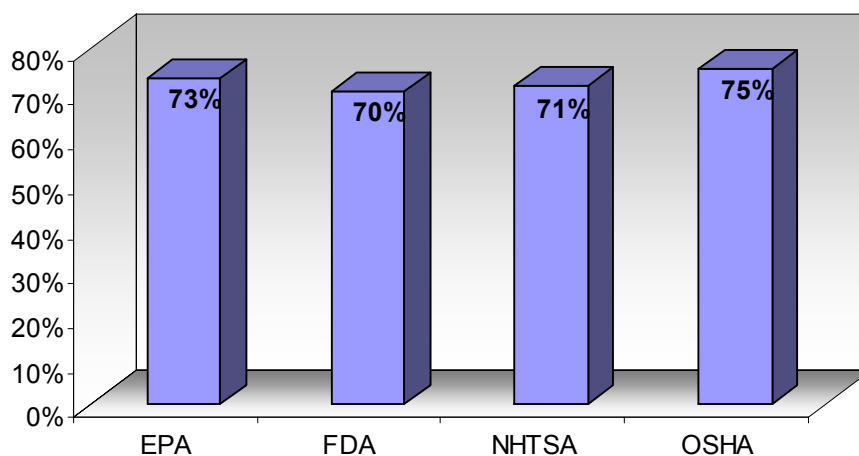
When explaining OSHA's decision to abandon work on large numbers of identified needs, agency head John L. Henshaw argued that he was converting the agenda from a "wish list" to a "to-do list."¹² OSHA and the other agencies studied in this analysis have actually made their agendas a do-nothing list.

We looked at major benchmarks announced in the December 2003 Unified Agenda as due for completion before the June 28, 2004 publication of the spring agenda. We focused on deadlines for advance notices of proposed rulemaking, notices of proposed rulemaking, final rules, and decisions on petitions for rulemaking. When we compared the fall deadlines with the status of those benchmarks in the spring 2004 agenda, we found a pattern of utter inaction. As shown in Figure 2 and detailed in Table 1, all

10. See 69 Fed. Reg. 7,351 (Feb. 17, 2004) (completing work on RIN 1218-AB97 (Commercial Diving Operations: Revision)).

11. See RINs 1218-AA68 (Scaffolds in Shipyards) (which received fourteen comments in one phase and an additional eight comments afterward) & -AA70 (Access and Egress in Shipyards) (which received thirteen comments).

12. See Goldstein & Cohen, *supra* note 7, at A1 .

Figure 2**Failure Rate in Meeting
Agenda Benchmarks**

Benchmarks from Dec. 2003 agenda scheduled for completion by June 2004 but not achieved

four agencies failed to meet 70 percent or more of their benchmarks: EPA failed to meet 73 percent of its benchmarks; FDA, 70 percent; OSHA, 75 percent; and NHTSA, 71 percent.

Not only has the administration failed to meet large numbers of its own benchmarks in the last six months, but it has also continued to allow documented, long-identified needs to languish on agency agendas. These items include the following.

- Tire pressure monitoring systems: A rule to require systems that would alert drivers when tire pressure is dangerously low was finished but found to be so inadequate that a court vacated it and sent the agency back to the drawing board. NHTSA has failed to produce a suitable rule since then. In court papers, in fact, NHTSA revealed that the White House has stalled the revised rule.

Table 1

Failure to Meet Agenda Benchmarks

About this Table: Comparing deadlines in the December 2003 Unified Agenda that were to occur by June 2004 with what was listed in the June 2004 Unified Agenda.

	Number Items to Be Achieved	Number Items Completed	Number of Items Not Completed	Percent Not Completed
EPA	183	49	134	73%
FDA	40	12	28	70%
NHTSA	49	14	35	71%
OSHA	8	2	6	75%

Note: Includes only advance notices of proposed rulemaking, notices of proposed rulemaking, petition decisions, and final rules.

- Mad cow safeguards: Despite promises in January to close a loophole that could allow mammalian proteins in cow feed, thus increasing the risk of cow-to-cow feeding that could pass on mad cow disease, the FDA has downgraded its proposal to long-term status—meaning that an actual rule is not foreseeable in the next 12 months.
- Worker exposure to hexavalent chromium: Although approximately one million workers are exposed to hexavalent chromium, and hundreds die prematurely every year from lung cancer because of that exposure, OSHA has allowed a rule to address the problem to languish on its agenda for years. Nine years after OSHA had been petitioned to address the problem, a federal court ordered the agency to complete the rulemaking by October 2004.¹³

¹³. See *Public Citizen Health Res. Grp. v. Chao*, No. 02-1611, 2003 WL 22158985 (3d Cir. April 2, 2003) (order); *Public Citizen Health Res. Grp. v. Chao*, 314 F.3d 143 (3d Cir. 2002) (decision).

Continuing to Place Special Interests Over the Public Interest

The administration continues to produce few major protections of the public interest, and those it does produce are generally weak, putting corporate special interests over the public interest. The public is not getting the protections it needs and deserves from its own government.

We started by looking at economically significant completed actions reported in the last two editions of the Unified Agenda. “Economically significant” actions are those that are estimated to impose \$100 million or more annually in economic consequences; accordingly, they are a reasonable proxy for measuring the administration’s output of important protections of the public interest. Even disregarding “completed” items that were withdrawn altogether, the administration’s record is abysmal:

- EPA completed only three economically significant items on its last two agendas, one of which was not even a rulemaking but represented only the perfection of a record that had been challenged on appeal, whereas the other two have been challenged in court for insufficiently protecting the environment.
- The FDA likewise completed only three economically significant items, one of which will not be effective for several years while the other two are tilted in favor of regulated industry. One rule, which limits certain patent filings that can delay entry to the market of generic pharmaceuticals, still leaves uncompleted other important steps needed to stop major drug companies from blocking inexpensive generics.
- NHTSA completed a large number of agenda items in the last year, although only half of them were actually rules. The completed rules, which address auto safety concerns ranging from the prevention of post-crash fires to development of an early warning database of potential defects and safety hazards, are generally weak and shield the auto industry from accountability.

- OSHA’s record of completed actions is essentially empty. Over the last year, OSHA can only point to three items that were completed, and one of those was not a new rule but only an analysis of a pre-existing rule’s economic consequences. One of the two completed rules actually does not address a problem but instead sweeps one under the rug by eliminating data collection of musculoskeletal disorders. OSHA has yet to produce a single economically significant protection of workplace health or safety since the Bush administration took office.

Simply counting up the number of economically significant completions can, however, create a distorted picture of regulatory output, for several reasons. First, the agencies include both actually finalized rules and rules withdrawn altogether from their priority lists in their table of “completed” actions. Second, a variety of activities other than rulemakings can appear alongside rules on the agendas:

- Some agencies include “section 610 reviews” along with rulemakings on their agendas. These reviews, required by the Regulatory Flexibility Act, are periodic examinations of existing rules’ economic consequences for “small businesses” as defined by the Small Business Administration.
- NHTSA includes petitions for reconsideration of recently completed rules as separate items on its agenda. In the case of its attempts to issue a rule on tire pressure monitoring systems, its entry for petitions for reconsideration of the eventually vacated rule was marked as economically significant.
- The same rulemaking endeavor can appear multiple times on the agenda. Take the example of NHTSA’s tire pressure monitoring system rule, as shown in Figure 3. The rule was vacated by the court as an inadequate effort that failed to comply with the statutory mandate and was too industry-friendly. NHTSA has now gone back to the drawing board, and

Figure 3**How Failure Looks Like Work: *Tire Pressure Monitoring Systems***

- (1) **COMPLETED:** First attempt to create a rule (RIN 2127-AI33) is added to agenda and eventually recorded as completed
- (2) **PROPOSED:** NHTSA adds agenda item — marked as economically significant — tracking its review of petitions for reconsideration of that rule (RIN 2127-AI90)
- (3) **COMPLETED:** When the federal court rejects the rule as not complying with the law, NHTSA adds agenda item (RIN 2127-AJ22) recording its erasure of the rule
- (4) **COMPLETED:** Agenda item tracking petitions for reconsideration is withdrawn and added to “completed actions” table
- (5) **PROPOSED:** NHTSA’s new attempt at a rule is entered on agenda with a new RIN (2127-AJ23)

its new attempt is being tracked on its agenda as an altogether new rulemaking activity with a new identifying number (RIN). A cumulative count of NHTSA’s agendas during the Bush administration would pick up this rulemaking twice.

Another way of looking at the administration’s record of completed action is to consult a database of information released by the Office of Information and Regulatory Affairs inside the White House’s Office of Management and Budget. An obscure and secretive office, it wields enormous power as the White House’s vehicle for implementing and aborting regulatory priorities. Agencies are required, by White House orders, to submit notices and proposed or final major rules to OIRA before they can be published in the *Federal Register*. OIRA, in turn, maintains a database tracking what it receives from the agencies and OIRA’s decisions. After years of advocacy by groups such as OMB Watch, OIRA has begun, under the leadership of current administrator John Graham, to make this information publicly available in a useable form.

The database actually only records OIRA’s reviews of submitted rules, not the actual final publication of rules. For a close approximation of agency output, we looked for economically significant rules submitted to OIRA in the final stage which OIRA subsequently approved for publication. To be

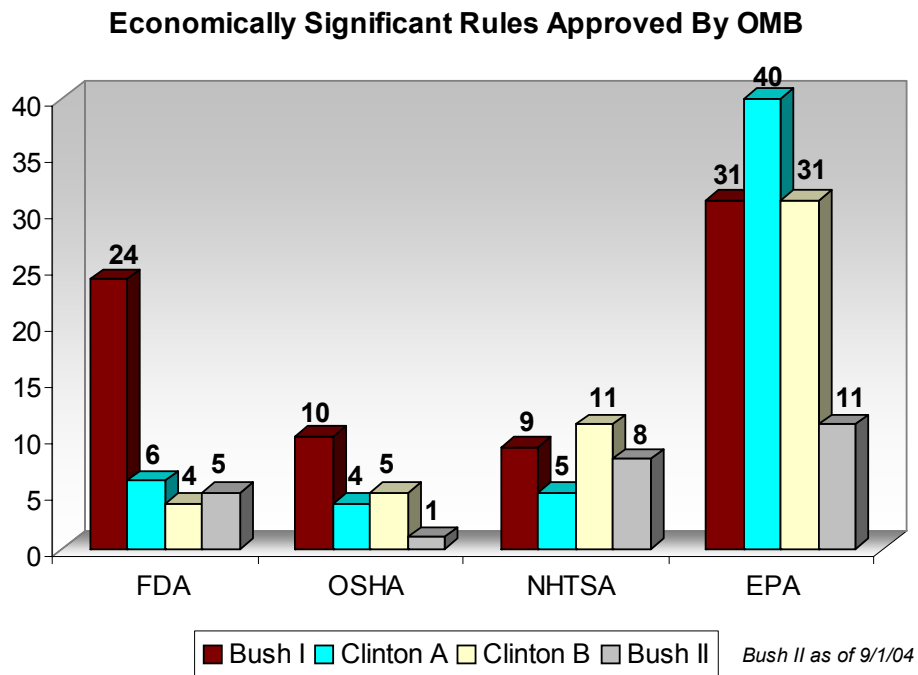
generous, we expanded the date range and looked for the output of these economically significant rules as recently as September 1, 2004.

This database can produce a misleadingly inflated picture of regulatory output. For example, the same NHTSA tire pressure monitoring rulemaking that distorts NHTSA's record in the Unified Agenda also inflates its record of activity in the database. The vacated rule shows up in the database as a completed economically significant rule, and NHTSA's new attempt at a tire pressure monitoring rule is now logged in the database under a new identifying number (or RIN); when a final rule is ultimately issued, it will also show up in that database as a second completed economically significant rule, even though the first was vacated by the court and the second is merely a renewed attempt at the same rulemaking. NHTSA's record of completed major rules is further inflated because every application of NHTSA's long-standing fuel economy standards to a new year's makes and models gets logged as a separate rulemaking, even when the standards themselves have not been adjusted.

Further, the information only reflects the status of a rule when it arrived at OMB and then left it as approved for publication. For example, this database shows that OSHA released one economically significant rule in 2002, but that rule was not actually published in the *Federal Register* until June 2003.¹⁴ When OIRA reviewed the rule (which eliminates the requirement that employers report musculoskeletal disorders as a distinct category of workplace health and safety problems), it was designated as economically significant; when OSHA released it, it was not so designated. OMB's database, then, would suggest that OSHA released an economically significant rule in 2002, whereas further scrutiny reveals that OSHA has yet to release an economically significant workplace health or safety protection during this administration.

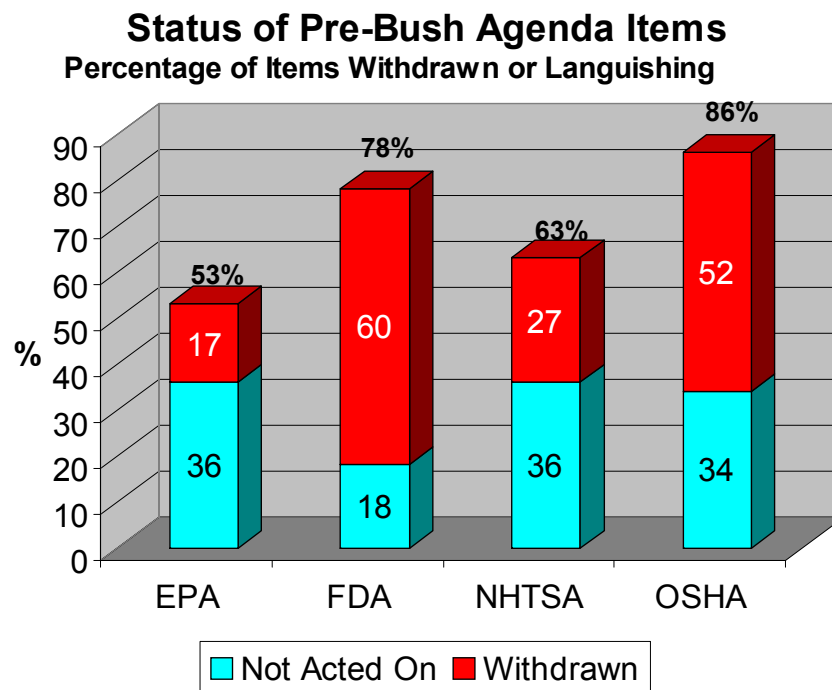
Even with this potential for inflated numbers, the OIRA information reveals a shockingly poor picture of the administration's record. As shown in Figure 4 below, the Bush administration has produced few economically significant rules, especially compared with past administrations of both parties. This meager output is all the more troubling because so many clearly identified priorities for action that were on the agendas when the Bush administration

14. This database is available in list form on-line at <<http://www.whitehouse.gov/omb/library/OMBARYTD-2002.html#DOL>>. Searching for "1218-AC06" hits the database entry showing OIRA considering an economically significant rule and approving it for publication in June 2002. The published rule, *see* 68 Fed. Reg. 38,601 (June 30, 2003), was released a full year later and was designated as not economically significant.

Figure 4

took office—a significant majority, in fact, ranging from 53 percent at EPA to 86 percent at OSHA—have been abandoned or remain unaddressed, as shown in Figure 5. The total picture from the last four years is one of an administration that has utterly abdicated its responsibility to give us all the protections we need and deserve.

Beyond these illustrative figures, the qualitative information about items completed during the last year reveals the same pattern of failure. Using the last two editions of the Unified Agenda as a starting point, we found that the administration continued its trend of issuing rules that are distorted to serve industry interests and therefore threaten to exacerbate the very problems they should be correcting. Here are some of the most egregious examples:

Figure 5

- Workers' musculoskeletal disorders: Although there were approximately 1.6 million musculoskeletal injuries, of which 500,000 were so serious that workers missed time on the job, the Bush administration completed a rule that does not make workplaces safer but, instead, sweeps the problem under the rug by eliminating the requirement that MSDs be reported separately rather than be lumped in with the total number of workplace injuries.
- Early warning: In the aftermath of the Ford/Firestone tire problem, Congress required NHTSA to create a database collecting information from automaker reports and consumer experiences that, combined,

would help NHTSA and the public learn early about potentially life-threatening defects. NHTSA's rule creates that database but keeps it secret and completely unavailable to the public.

- New source review: Older power plants that make major upgrades are currently required to bring their emission standards up to the levels required of new power plants, but existing regulations exempted the older facilities from this heightened burden when performing routine maintenance. Power plants have exploited this loophole to conduct extensive upgrades of older facilities and avoid compliance with more stringent anti-pollution measures. A rule completed in this agenda period would have authorized such questionably legal practices by expanding the definition of "routine maintenance" to permit older polluting power plants to continue avoiding up-to-date pollution regulations while extensively upgrading their facilities. A legal challenge has prevented it from going into effect.
-

In the sections that follow, we present analyses of the regulatory record for the last year in the four selected agencies. To complement those studies, we are also providing the underlying details in two useable formats:

- tracking charts that show each agency's cumulative agenda progress during this administration, and
- tables that list rules withdrawn by the selected agencies (and, additionally, the Mine Safety and Health Administration) and set the agency's reasons for adding each rulemaking to the agenda in the first instance alongside its subsequent reasons, if any, for dropping the item.

These charts are available, along with digital copies of this analysis, on our website at <<http://www.ombwatch.org/regs/patternoffailure>>.

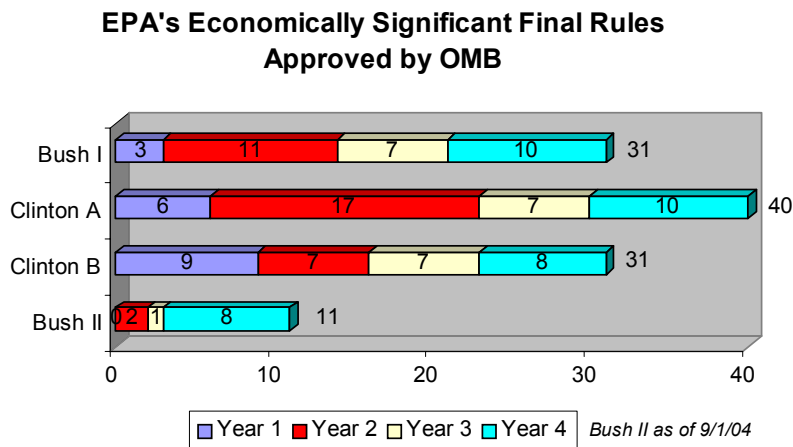
EPA: Withering on the Vine

During the last year, the Environmental Protection Agency (EPA) has continued its record of doing little for the environment. Compared to past administrations, including the Bush I administration, the Bush II EPA is a regulatory nonentity. What little it has done in this time shows a pattern of placing corporate interests over the public interest.

Floating With the Current: Items Completed

EPA's meager output of economically significant protections of the environment in the last year has furthered a larger pattern of failure that began when the Bush administration took office. The few economically significant rules the agency successfully ran through the OIRA gauntlet¹⁵ during the course of this administration pale in comparison to the output of past administrations, even the Bush I administration, as shown in Figure 6.

Figure 6



15. Approval by OIRA does not necessarily mean the rule was immediately published by the agency. See pages 20-21 *supra* (explaining the source—and limitations—of OIRA review data).

The December 2003 and June 2004 editions of the Unified Agenda reveal that EPA completed only three economically significant rules during the last year, and all three continue the administration's pattern of producing rules that favor industry. One of these, which would have favored polluters in the power industry, has been blocked by court order from going into effect. Another rule would have incorporated industry-suggested language aimed at limiting its scope, but a court challenge stopped the agency from doing so. The final economically significant item merely represents the agency's perfection of an administrative record that had been challenged on appeal; although there is nothing particularly industry-friendly in that completed action, it may soon be undermined by a Bush administration initiative that places polluters' interests above the public's interest in clean air.

Coal-Fired Power Plants: Permission to Pollute

The first of these economically significant completed actions is EPA's revision of its New Source Review requirements.¹⁶ Older coal-fired power plants were exempted from Clean Air Act standards because Congress believed they would be phased out over time. These older plants were required to enter into compliance with the Clean Air Act whenever they underwent major upgrades, as though they were "new sources," but routine maintenance and repair were exempted from the definition of major upgrade. EPA proposed in October 2003 to expand the routine maintenance loophole, despite evidence that power companies had long been abusing it in order to avoid Clean Air Act requirements.¹⁷ This completed action has been stalled by court challenge.¹⁸

16. See RIN 2060-AK28 (New Source Review: Routine Maintenance, Repair and Replacement). Although those who follow environmental issues generally refer to rulemakings by their agency docket number, those numbers are not used in the Unified Agenda. (Some agenda items actually track potential rulemakings for which the agency has not yet opened a docket, in addition to activities such as research projects for which docket numbers are occasionally inapposite.) In order to facilitate cross-references between the Unified Agenda, this analysis, and the related tracking chart and table of withdrawn items (available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>), we are adopting the agenda practice of referring to items by their RINs.

17. See New Source Review, 68 Fed. Reg. 61,248 (Oct. 27, 2003).

18. See *Special Interest Takeover*, *supra* note 3, at 14-16.

Emission Standards for Automakers

Another economically significant rule completed in the last year governs hazardous air pollution emissions from surface coating operations applying topcoats to automobiles and light trucks or coating of vehicle body parts.¹⁹ Other rulemakings likewise setting national emission standards adopted industry-supplied language for “risk-based” exemptions from stringent technology requirements.²⁰ “Risk-based” exemptions are a form of regulatory triage in which EPA exempts some polluters from emission standards based on the level of health risks posed to surrounding communities. A court challenge and the ticking of the clock, however, prevented EPA from adding that language to this rule:

Based on our consideration of the comments received and other factors, we have decided not to include the risk-based approaches in today’s final rule. The risk-based approaches described in the proposed rule and addressed in the comments we received raise a number of complex issues. In addition, we are under time pressure to complete the final rule, because the statutory deadline for promulgation has passed and a deadline suit has been filed against EPA. . . . Given the range of issues raised by the risk-based approaches and the need to promulgate a final rule expeditiously, we feel that it is appropriate not to include any risk-based approaches in today’s final rule.²¹

19. See RIN 2060-AG99 (National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks).

20. See OMB Watch, “Industry, OMB Press EPA to Offer Exemptions to Clean Air Standards,” available on-line at <<http://www.ombwatch.org/article/articleview/1382>>.

21. 69 Fed. Reg. 22,602, 22,617 (April 26, 2004).

Nonetheless, this industry-favored exemption could re-emerge in the future: “This determination does not preclude future consideration of similar or other risk-based approaches for this source category in the future.”²²

Clear Skies: Ozone

The final “completed” item²³ essentially only tidies up the record justifying two rulemakings completed long ago. In response to a petition by several northeastern states that ozone and ozone-precursors such as nitrogen oxide (NOx) emitted by polluters in upwind states were traveling downwind and preventing the petitioner states from attaining air quality standards, EPA called in October 1998 for the upwind states to revise their air quality implementation plans and followed up in January 2000 by establishing NOx emission limits for major sources of the pollutants. Each of these decisions was challenged on appeal,²⁴ and each was remanded back to EPA because the underlying basis for the rulemaking required fuller explanations. EPA opted to retain both the call for improved implementation plans and the emission limits that had been challenged and simply perfected its record. A subsequent court decision in April 2004 upheld these actions,²⁵ leaving the agency free to announce the termination of this agenda item on its June 28, 2004 agenda.

The agency’s past decisions on NOx emissions may soon be undermined, however, by a recent Bush administration proposal. In January of this year, the EPA proposed²⁶ to regulate NOx emissions through its “Clear Skies” initiative, the centerpiece of which is “flexibility” and a market-styled

22. *Id.* at 22,617-18.

23. See RIN 2060-AJ20 (Rulemakings for the Purpose of Reducing Interstate Ozone Transport).

24. See *Appalachian Power Co. v. EPA*, 251 F.3d 1056 (D.C. Cir. 2001); *Appalachian Power Co. v. EPA*, 249 F.3d 1032 (D.C. Cir. 2001).

25. See *West Virginia v. EPA*, 362 F.3d 861 (D.C. Cir. 2004).

26. See RIN 2060-AL76 (Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Interstate Air Quality Rule)). See also Clean Air Interstate Rule, 69 Fed. Reg. 4,566 (Jan. 30, 2004).

“cap-and-trade” program.²⁷ Both anti-regulatory buzzwords refer to approaches opposed to traditional uniform rules, which are disparaged as the “command-and-control” approach. “Flexibility” is a supposed benefit of “cap and trade,” in which polluters are given a capped number of “credits”—essentially, limited rights to pollute—which can then be traded with other companies, the result being that some companies will be allowed to pollute more than others while the total pollution emissions are notionally restricted by the limited number of total credits.

The key terms here are chosen by design to sound neutral (“cap and trade”) and even positive (“flexibility”) in comparison to a traditional across-the-board requirement that polluters must implement the best pollution-reducing technology (dismissed as the negative-sounding “command-and-control”). The value connotations attached to the language mask the inequities that this initiative will implement for people and localities. A fair across-the-board requirement would mean that all companies would be required to implement a minimum level of technology, above which more community-minded companies could always seek to perform. The alternative to a fair, equitable rule means that some companies will be allowed to pollute more than others, and the communities sited near them will be subjected to more intense levels of emissions than others.

Lost in the Smog: Items Withdrawn

In the past year, EPA withdrew 25 items from the Unified Agenda, almost half of them (12) coming from Clean Water Act items. This year’s withdrawals bring the EPA’s total to 90 during this administration, of which 66 were items carried over from past administrations. Most of these withdrawn items came from three areas of the EPA’s agenda: 39 from Clean Air Act items, 16 from Clean Water Act items, and 12 from Resource Conservation and Recovery Act (RCRA) items.²⁸

27. For more on the Bush administration’s Clear Skies initiative, see the White House page at <http://www.whitehouse.gov/news/releases/2002/02/clearskies.html>.

28. Details on these 67 items are available in the cumulative tracking chart of EPA agenda actions and the chart of EPA withdrawn items, both of which are available on-line at <http://www.ombwatch.org/regs/patternoffailure>.

Among the items withdrawn in the last year are the following:

- a rule proposed back in 1995 to set hazardous air pollution emission standards for paint stripping operations;²⁹
- final decisions on 40 chemicals and one chemical category which had been deferred (because of “difficult technical or policy issues”) from a 1994 decision to add many other chemicals and chemical classes to community right-to-know regulations;³⁰ and
- restrictions on locating city landfills near airports, in order to prevent birds attracted to the landfills from endangering aircraft operations, originally proposed in July 2002.³¹

Also withdrawn in this period, although not recorded as such on the spring 2004 agenda, was a proposal to regulate construction runoff.³² Construction sites annually discharge an estimated 80 million tons of solids into U.S. waterways, but EPA abandoned (at the urging of the White House) work on a proposal to require an 80 percent reduction in storm water discharges during and after construction.³³

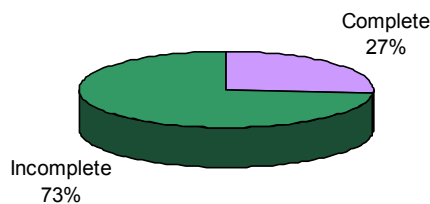
29. See RIN 2060-AG26 (NESHAP: Paint Stripping Operations).

30. See RIN 2025-AA01 (TRI; Chemical Expansion; Finalization of Deferred Chemicals).

31. See RIN 2050-AE91 (Municipal Solid Waste Landfill Location Restrictions for Airport Safety). EPA issued parallel proposals at 67 Fed. Reg. 45,915 (July 11, 2002) and 67 *id.* 45,948 (July 11, 2002).

32. See RIN 2040-AD42 (Effluent Limitations Guidelines and New Source Performance Standards for the Construction and Development Category). Although the spring 2004 agenda was published June 28, 2004 and this item was withdrawn in April 2004, see Effluent Limitations Guidelines and New Source Performance Standards for the Construction and Development Category, 69 Fed. Reg. 22,472 (April 26, 2004), it was listed on the agenda not as withdrawn but as being in the “final rule stage,” with completion expected some time during the remaining days of June 2004.

33. See *Special Interest Takeover*, *supra* note 3, at 49-50.

Figure 7**EPA Benchmarks Listed Fall 2003
To Be Completed Spring 2004**

EPA did not explain these withdrawals in the Unified Agenda. Aside from cases in which items were consolidated³⁴ or were direct final rules withdrawn after the agency received negative comments,³⁵ EPA has not otherwise explained its decisions to withdraw items from its agenda. Explanations help make the agencies accountable to the public; EPA's failure to explain these withdrawals makes its principles for setting priorities so inscrutable that it is difficult for the public to agree or disagree with them.

Stuck in the Mud: Continued Inaction

With so many items withdrawn from the agenda over the last four years, EPA should have been able to devote resources to long-identified needs

34. See RINs 2040-AC95 (Test Procedures for the Analysis of Miscellaneous Metals, Anions, and Volatile Organics Under the Clean Water Act, Phase One), -AD12 (Test Procedures for the Analysis of Miscellaneous Metals, Anions, and Volatile Organics Under the Clean Water Act, Phase Two), -AD52 (Test Procedures for the Analysis of Mercury Under the Clean Water Act, Method 245.7), & 2070-AD62 (Endangered Species and Pesticide Regulation).

35. See RINs 2040-AD97 (Effluent Guidelines and Standards for Pharmaceutical Manufacturing: Amendment), 2050-AE91 (Municipal Solid Waste Landfill Location Restrictions for Airport Safety), & 2060-AL82 (Revisions to Federal Operating Permits Program Fee Payment Deadlines for California Agricultural Sources).

that continue to languish on its agenda. Comparing EPA's December 2003 and June 2004 agendas, however, reveals a pattern of inaction. EPA failed to achieve fully 73 percent of the benchmarks announced in the December agenda that were due to be completed by June 2004, as shown in Figure 7.³⁶ In that same time, EPA downgraded 30 of its agenda items to long-term status, which means that the item will remain on the agenda although no final action is foreseeable within the next year.³⁷

The EPA's failure to act means that compelling needs, such as the following, are going unaddressed:

- drinking water regulations for radon, disinfectants and disinfection by-products, and drinking water treatment,³⁸ all downgraded to long-term status—even though two of the items have been lingering since November 1999 and the third dates back at least as far as the Bush I administration;³⁹
- criteria for designating hazardous substances under the Superfund law, lingering since the April 1999 agenda;⁴⁰ and
- a proposed ban on lead fishing sinkers, which first appeared on the October 1990 agenda.⁴¹

36. For more details on our analysis of agency benchmarks, see page 15 *supra*.

37. More details on these agenda items are available in the cumulative tracking chart for EPA agendas, which can be found on-line at <<http://www.ombwatch.org/regs/patternoffailure>>.

38. See RINs 2040-AD37 (National Primary Drinking Water Regulations: Long-Term 2 Enhanced Surface Water Treatment Rule), -AD38 (National Primary Drinking Water Regulations: Stage 2 Disinfectants/Disinfection Byproducts Rule), & -AA94 (National Primary Drinking Water Regulations: Radon).

39. The drinking water treatment rule, RIN 2040-AA94, appears as far back as the October 1989 agenda, while the remaining items (RINs 2040-AD37 and -AD38) first appeared on the November 1999 agenda.

40. See RIN 2050-AE63 (Criteria for the Designation of Hazardous Substances Under CERCLA Section 102(a)).

41. See RIN 2070-AC21 (Lead Fishing Sinkers; Response to Citizens Petition and Proposed Ban).

FDA: In Critical Condition

The Food and Drug Administration (FDA) withdrew a large number of identified food and drug safety priorities—48 in all, or almost half of all the items then on the agenda—in May 2002, and in the last year the agency withdrew three more. With so much room cleared for work on new priorities, the FDA has nonetheless failed to produce much. Over the last year, the FDA has produced only three economically significant rules, and it has quietly withdrawn or delayed important actions on such vital issues as mad cow disease and warnings for recipients of contaminated blood products.

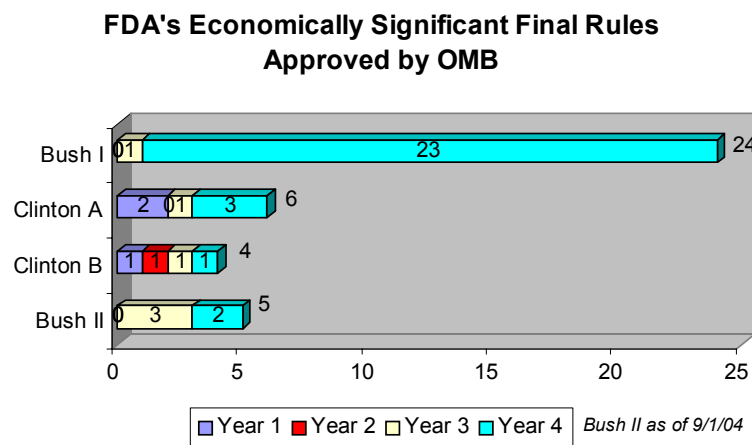
Band-Aids: Items Completed

The FDA's meager output of economically significant protections of the public health in the last year has furthered a larger pattern of failure that began when the Bush administration took office. The FDA's few economically significant final rules that won OIRA approval⁴² during the course of this administration pale in comparison to the output of the Bush I administration, as shown in Figure 8.

Although the Bush II rate of output appears to be on par with that of the Clinton administration, the rules themselves are weaker than needed. The FDA completed 27 agenda items in the last year, of which 10 were reviews of the over-the-counter status for individual categories of drugs. Only three of the completed items were economically significant rules. One, requiring bar code labels on drugs in order to reduce the risk of administering the wrong drugs to the wrong patients,⁴³ will not be effective for several years.

42. Approval by OIRA does not necessarily mean that a rule was immediately published by the agency. See pages 20-21 *supra* (explaining the source—and limitations—of OIRA review data).

43. See RIN 0910-AC26 (Bar Code Label Requirements for Human Drug Products). Although those who follow food and drug safety issues generally refer to rulemakings by their agency docket number, those numbers are not used in the Unified Agenda. (Some agenda items actually track potential rulemakings for which the agency has not yet opened a docket, in addition to activities such as research projects for which docket numbers are occasionally inapposite.) In order to facilitate cross-references between the Unified Agenda, this analysis, and the related tracking chart and table of withdrawn items (available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>), we are adopting the agenda practice of referring to items by their RINs.

Figure 8

Another, which limits the ways pharmaceutical companies can file certain additional patents in order to delay entry to the market of generic counterparts,⁴⁴ still leaves unaddressed the problem of brand-name makers paying the generic companies to keep their less expensive alternatives off the market. Further, the administration opposed a Senate bill, the Greater Access to Affordable Pharmaceuticals Act, that would have strengthened the rule by giving generic drug companies the ability to challenge in court such generic-delaying patents inappropriately listed with the FDA.⁴⁵

The final significant completed rule, which has been proudly touted by OIRA Administrator John Graham as a major achievement of this administration, requires food labels to list the amount of trans-fatty acids.⁴⁶ Found in food products such as vegetable shortening, snack foods, fried foods, and salad dressings, trans fats are linked with an increased risk of coronary

44. See RIN 0910-AC48 (Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Application).

45. See Public Citizen, "Bush's Proposed Generic Drug Rule: Days Late, Billions of Dollars Short," available on-line at <<http://www.citizen.org/pressroom/release.cfm?ID=1250>>.

46. See RIN 0910-AB66 (Food Labeling: Trans Fatty Acids in Nutrition Labeling and Nutrient Content Claims).

heart disease. Although a meaningful step forward, the final rule is still weaker than originally proposed by the Clinton FDA. The new standards omit a provision from FDA's 1999 proposal that would have required trans-fatty acids to be included in the amount and percent Daily Value declared for saturated fatty acids (also linked with heart disease). Canada requires food manufacturers to label trans fat in this way. "The new labels will let consumers compare trans fat content from product to product, and that will be a great step forward," said Margo Wootan, policy director at the Center for Science in the Public Interest. "It will be hard, though, for people to tell if a given number of grams of trans fat is a lot or a little. Five grams may not seem like a lot, but it is."⁴⁷

Malpractice: Items Withdrawn

The FDA withdrew four more items from the agenda this year, bringing its total of withdrawn items to 62 (of which 52 were first proposed by the Clinton administration). Of the four withdrawn this year, one (dealing with waivers of informed consent for administering experimental drugs to military personnel) was essentially preempted by statute,⁴⁸ while another would have simply consolidated two separate sets of standards for licensed and unlicensed manufacturers of medicated feed into one set of standards for both.⁴⁹ The two remaining withdrawn items, however, are particularly troubling.

Protecting the Blood Supply: Patient Notification

The FDA's decision to withdraw a long-pending rule to protect the blood supply from infectious agents is alarming. Although related blood

47. See *Special Interest Takeover*, *supra* note 3, at 69 text accompanying notes 42-43.

48. A long-pending rule change regarding the waiver of informed consent when administering experimental drugs to military personnel would have completed the FDA's work of stepping out of that role, which was essentially foreclosed already by statute and court challenges. The rulemaking is likely to be made unnecessary by a provision in the Department of Defense's appropriations bill for next year. See RIN 0910-AA89 (Determination that Informed Consent is Infeasible or Is Contrary to the Best Interest of Recipients); see also Department of Defense Authorization Act for Fiscal Year 2005, S.2400, 108th Cong. § 716 (2004).

49. See RIN 0910-AB70 (Current Good Manufacturing Practice for Medicated Feeds).

supply rules were completed or otherwise left on the agenda, the FDA decided in June to drop a proposed rule that would have required a tracking system for blood-derived products to follow from the manufacturer to a patient receiving the product.⁵⁰ Such a system was deemed necessary to ensure that health care providers and patients, especially those who receive large batches of plasma-derived products that they self-administer over time, could be notified in the event of a recall or evidence suggesting a particular product could be contaminated.⁵¹ The need for an improved notification system was identified in a 1996 House report,⁵² and the FDA added this item to its agenda in August 1999 out of the concern that any voluntary system not mandated across-the-board or otherwise enforceable by the government could not adequately ensure patient notification.

Its rationale for adding the item to its agenda was compelling. “[V]oluntary programs for notifying recipients . . . are fairly new,” the agency explained. “Thus the success of the voluntary programs cannot yet be fully assessed. However, the success of such voluntary programs will always depend on the continued voluntary support by manufacturers of blood products and the continued vigorous recruitment of patients/recipients to encourage full participation. FDA is concerned that the continued success of patient notification cannot be assured without regulatory standards . . . and without a clear mechanism of enforcement in the event a notification program is found deficient.”⁵³ Despite this clear statement of an important problem to be addressed by the potential rulemaking, the FDA withdrew the item from its spring 2004 agenda without explanation.

50. See RIN 0910-AF02 (Plasma Derivatives and Similar Recombinant-Based Products; Requirements for Notification of Recalls and Withdrawals).

51. See Requirements for Tracking and Notification for Plasma Derivatives and Other Blood-Derived Products, 64 Fed. Reg. 45,383 (Aug. 19, 1999).

52. See *Protecting the Nation’s Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats*, H.R. Rep. No. 104-746 (1996) (also available on-line at <<http://www.bloodbook.com/FDA-congres.html>>).

53. See 64 Fed. Reg. at 45,383.

Preventing Mad Cow Disease

Another FDA withdrawal was an element of the comprehensive regulatory framework by which both the FDA and the Department of Agriculture monitor and prevent mad cow disease from contaminating the human food chain. The USDA maintains a list of countries in which mad cow disease has been recorded and that present an undue risk of introducing mad cow into the United States. An FDA proposal, added to the agenda in May 2001, would have restricted from FDA-regulated products (which include foods other than meat as well as dietary supplements and cosmetics) the use of most materials from cattle born, raised, or slaughtered in a country on the USDA's list.⁵⁴ The rule was withdrawn from the Unified Agenda this June without explanation.

Bad Medicine: Continued Inaction

Meanwhile, another element of FDA's mad cow regulation has quietly been delayed. Although the FDA and USDA announced with great fanfare their efforts to strengthen protections against mad cow disease,⁵⁵ their announcement concealed FDA's decision to renege on its promise to close a loophole in the ban on mammalian proteins from ruminant feed. The only known way for mad cow to spread from one cow to another is to feed proteins from an infected ruminant. An existing FDA regulation bans the feeding of mammalian proteins to ruminants, including bovines, but the rule still allows for the feeding of chicken litter to cows. Since the chickens are fed cow proteins, it is possible that the chicken litter is contaminated with cow protein which is then fed back to the cows in the form of chicken litter.⁵⁶ The FDA promised back in January that this loophole would be closed, but it decided

54. See RIN 0910-AC19 (Use of Materials Derived from Bovine and Ovine Animals in FDA-Regulated Products).

55. See "USDA and HHS Strengthen Safeguards Against Bovine Spongiform Encephalopathy," press release on-line at <<http://www.fda.gov/bbs/topics/news/2004/NEW01084.html>>.

56. See OMB Watch, "Mad Cow Disease Regulation Fails to Protect U.S. Food Supply," available on-line at <<http://www.ombwatch.org/article/articleview/2308>>.

this July only to issue an Advance Notice of Proposed Rulemaking, with an uncertain schedule for any actual rule to be issued.⁵⁷

This proposed rule joins several others that have been languishing on FDA's agenda, among them the following:

- 14 items on the agenda at the time the Bush administration took office that have not since been completed or withdrawn—at least two of which have been on the agenda since November 1995;⁵⁸
- two components separated from a larger initiative to address infant formula, which was launched in July 1996;⁵⁹
- two remaining elements of an initiative to ensure blood safety that has been on the agenda since April 1998;⁶⁰ and
- 13 components separated from the larger task of over-the-counter status reviews that were begun in December 2002.⁶¹

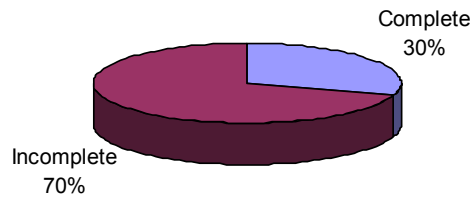
57. See Federal Measures to Mitigate BSE Risk, 69 Fed. Reg. 42,288, 42,293 (July 14, 2004); Consumers Union, "FDA Betrays Public Trust, Reneges on Promise to Quickly Reduce Mad Cow Risk in Animal Feed," available on-line at <<http://www.consumersunion.org/pub/campaignmadcow/001237.html>>.

58. The two items that have lingered since 1995 are RINs 0910-AA49 (Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics) & -AA61 (Investigational New Drugs: Export Requirements for Unapproved New Drug Products). The remaining items can be identified on the NHTSA tracking chart available on-line at <www.ombwatch.org/regs/patternoffailure> by checking the column for Fall 2000, which was the last Clinton administration agenda.

59. The larger initiative was RIN 0910-AA04 (Infant Formula), and the remaining components are RINs 0910-AD81 and -AD77.

60. The larger initiative was RIN 0910-AB26 (Blood Initiative), and the remaining components are RINs 0910-AB96 (subsequently merged into RIN 0910-AF26) and -AF00 (now merged into RIN 0910-AF25).

61. The combined agenda item was RIN 0910-AA01 (Over-the-Counter (OTC) Drug Review), and the remaining OTC components are listed as RINs 0910-AC68, -AC85, -AC96, -AC98, -AC93, -AC72, -AD06, -AD07, -AD19, -AD25, -AD31, -AD33, and -AD43.

Figure 9**FDA Benchmarks Listed Fall 2003
To Be Completed Spring 2004**

These failures to act are part of a larger pattern of failure. In the six-month span between the December 2003 and June 2004 editions of the Unified Agenda, the FDA failed to achieve fully 70 percent of the benchmarks announced in the December agenda that were due to be completed by June 2004.⁶² Thus, not only is the agency continuing to abandon work on documented needs, but it is also failing to produce significant work on its own priorities.

62. For more details on our analysis of agency benchmarks, see page 15 *supra*.

NHTSA: Driving in the Slow Lane

The National Highway Traffic Safety Administration (NHTSA) has erased a large number of proposed protections from its rulemaking agenda during the Bush administration, most in its May 2003 agenda, in which eleven rules were eliminated at once, eight of them with one pat explanation: “Given other priorities, the agency does not plan to take action in this area in the next year.”⁶³ Those “other priorities” have not, however, propelled NHTSA to significant action since then. Rules actually completed in the last year—only three of which are economically significant—are generally weak or shield the auto industry from accountability.

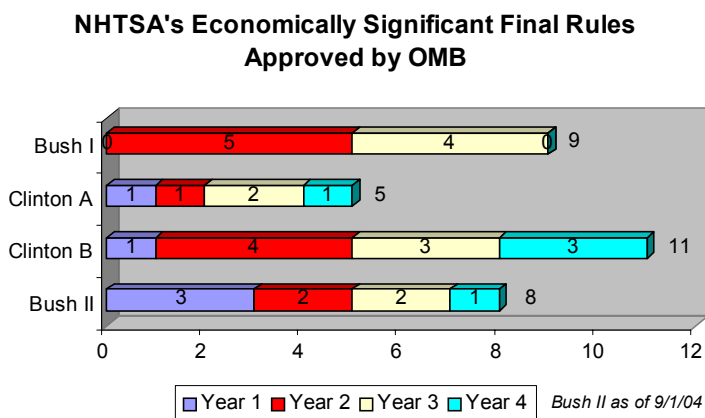
Lurching Forward: Items Completed

NHTSA’s record of securing approval from OIRA for economically significant final rules⁶⁴ during the Bush administration (as shown in Figure 10) is not, at first glance, dramatically lower than that of past administrations, but the underlying facts reveal a pattern of artificial accomplishment and failure to do what is necessary to ensure that the public is as safe as possible on the road.

Although many items are logged as completed actions in the fall 2003 and spring 2004 agendas, NHTSA has actually performed poorly in that time. NHTSA pads the “completed actions” chart in its agenda with items that are being merged into other entries, entries that reflect only the review of petitions for reconsideration of promulgated rules, and even entries for the withdrawal of priorities. Of the 51 entries that NHTSA logged as completed items in the fall 2003 and spring 2004 editions of the Unified Agenda, many are not even final rules at all.

63. For further details, consult the chart detailing NHTSA’s withdrawn items, accompanying this report on-line at <<http://www.ombwatch.org/regs/patternoffailure>>.

64. See pages 20-21 *supra* (explaining the source—and limitations—of OIRA review data).

Figure 10

- 14 represent “terminations” of agenda items, some of which were withdrawn outright while others were “completed” because they were merged into other agenda entries;⁶⁵
- one simply records that NHTSA was forced to return to the drawing board after a federal court vacated its rule on tire pressure monitoring systems, while another reflects that NHTSA closed out its review of petitions for reconsideration of that same rule;⁶⁶

65. For more information, see the NHTSA Tracking Chart, available for download on-line at <http://www.ombwatch.org/regs/patternoffailure>.

66. See RINs 2127-AI90 (Tire Pressure Monitoring System; Petitions for Reconsideration) & -AJ22 (Tire Pressure Monitoring System; Vacation of Standard). Although those who follow auto safety issues generally refer to rulemakings by their agency docket number, those numbers are not used in the Unified Agenda. (Some agenda items actually track potential rulemakings for which the agency has not yet opened a docket, in addition to activities such as research projects for which docket numbers are occasionally inapposite.) In order to facilitate cross-references between the Unified Agenda, this analysis, and the related tracking chart and table of withdrawn items (available on-line at <http://www.ombwatch.org/regs/patternoffailure>), we are adopting the agenda practice of referring to items by their RINs.

- four record NHTSA's handling of petitions for reconsideration;⁶⁷
- two represent publication of periodically collected data;⁶⁸ and
- one was a research study of an existing vehicle feature (researching the extent to which operators correctly use an airbag on-off toggle switch) rather than a rulemaking action.⁶⁹

Thus 23 of the 51 items listed as completed actions—nearly half of the total—result from a numbers game. Of the rules that have been completed, many are weaker than needed to address urgent auto safety issues. They include an inflated five-star SUV rollover score that is not required to be posted on the sticker at point of sale⁷⁰ and an air bag rule change that upgraded standards but reduced the percentage of the vehicle fleet required to comply.⁷¹ Of special interest are the following four rules.

Tire Safety

NHTSA was forced by the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act of 2000 to issue a rule improving the performance of tires.⁷² The TREAD Act was inspired by damning news coverage revealing, among other things, that Firestone tires had tread separation problems. The first improved tire safety standard in more than 30 years, the tire safety rule that NHTSA finally released on June 26,

67. See RINs 2127-AJ11 (Part 587; Offset Deformable Barrier, Petition for Reconsideration), -AJ25 (Partial Response to Petitions for Reconsideration; Federal Motor Vehicle Safety Standard—Glazing Materials), & -AJ30 (Partial Response to Petitions for Reconsideration; Federal Motor Vehicle Safety Standard—Occupant Crash Protection).

68. See RINs 2127-AI75 (Theft Data for Calendar Year 2000) & -AJ00 (Theft Data for Calendar Year 2001).

69. See RIN 2127-AH12 (Review: Air Bag On-Off Switches).

70. See RIN 2127-AI81 (Rollover Ratings).

71. See RIN 2127-AI71 (Advanced Air Bags).

72. See RIN 2127-AI54 (Improved Tire Safety).

2003 did require tires to undergo a low-inflation pressure test (seeking a minimum level of performance safety in tires when they are under-inflated to 20 pounds per square inch) and mandate high-speed and endurance tests.⁷³ Comparison of the proposed rule against the final rule reveals, however, that NHTSA required a less demanding endurance test and that it dropped several potential reforms, among them the following:

- a provision to address the deterioration of tire performance caused by aging;
- road hazard impact tests, which simulate a tire impacting a road hazard such as a pothole or curb; and
- modifications to the current “bead unseating” test, which is designed to evaluate how well a tire remains on the rim during turning maneuvers.⁷⁴

The agency also pushed back the effective date of these standards—giving manufacturers four years to comply, instead of a two- or three-year timetable as suggested in the proposal.

Fuel Integrity

NHTSA’s fuel integrity rule,⁷⁵ issued on December 1, 2003,⁷⁶ addresses the need to ensure that fuel systems do not cause deadly fires in a crash. Almost 16,000 drivers and passengers every year are exposed to a post-crash fire; 730 of them came away with moderate to severe burns, and three quarters of those had second- or third-degree burns over more than 90 percent of their body. NHTSA’s rule is so weak that most vehicles on the road actually pass the standard, *even the worst performing vehicles* known for killing hundreds annually in post-crash fires.⁷⁷

73. See FMVSS—Tires, 68 Fed. Reg. 38,116 (June 26, 2003).

74. See Public Citizen, “Tire Safety Standards: Tire Safety Performance Requirements Still Not Comprehensive,” available on-line at <http://www.citizen.org/documents/Chron_Tire.pdf>.

75. See RIN 2127-AF36 (Upgrade Fuel Integrity Performance Requirements).

76. See Fuel Systems Integrity, 68 Fed. Reg. 67,068 (Dec. 1, 2003).

77. See Center for Auto Safety, “CAS Petitions NHTSA for Stronger Fuel Integrity Standard,” available on-line at <<http://www.autosafety.org/article.php?did=870&scid=124>>.

Early Warning Systems

When a Houston reporter broke the story that Ford Explorers with Firestone tires were experiencing sudden tire blowouts then rolling over and killing the people inside, Congress was outraged to learn that an insurance investigator had given NHTSA information about a large number of fatal Ford/Firestone cases in the late 1980s, but to no avail because NHTSA had failed to investigate. Congressional investigation and follow-up press stories revealed both secret company memoranda and foreign recalls that U.S. regulators were never informed about. In reaction, Congress included in the TREAD Act a requirement that automakers submit information about potential defects to a new NHTSA early warning database that would combine industry knowledge and consumer reports. NHTSA's rule,⁷⁸ published in increments from June 2003 to April 2004,⁷⁹ does create the database, but NHTSA decided to keep the database information confidential, *even from a specific Freedom of Information Act request*. If NHTSA again sits on the information it receives, then the early warning database will warn no one.⁸⁰ Public Citizen and other groups are now challenging the policy in court.

Duel Fuel

NHTSA undermined the responsibility it has had since the 1970s to set fuel economy standards that reduce America's dependence on foreign oil. NHTSA was empowered by the Energy Policy and Conservation Act of 1975⁸¹ to issue average fuel economy standards for cars and other vehicles. The fuel economy standards apply not to individual makes or models but instead to a manufacturer's entire fleet for a given category of vehicle, averaged across all vehicles in a category (27.5 miles per gallon for passenger cars and 20.7 mpg

78. See RINs 2127-AI92 (Reporting of Information and Documents About Potential Defects), -AJ21 (Reporting of Information and Documents About Potential Defects), & -AJ38 (Reporting of Information and Documents About Potential Defects).

79. See 68 Fed. Reg. 35,145 (June 11, 2003); 68 *id.* 64,586 (Nov. 14, 2003); 69 *id.* 20,556 (April 16, 2004).

80. See Public Citizen, "Early Warning Database and Confidential Business Information," available on-line at <<http://www.citizen.org/autosafety/nhtsa/tread/earlywarning/>>.

81. Pub. L. No. 94-163, 89 Stat. 871 (1975).

for light trucks, which include SUVs, minivans, and pick-ups). NHTSA was further empowered by the Alternative Motor Fuels Act of 1988⁸² to encourage use of alternative fuels by granting credits toward average fuel economy requirements to automakers who manufacture “dual fuel” vehicles that can operate on either conventional fuel (gas or diesel) or a domestic alternative fuel such as methanol, ethanol, or natural gas. NHTSA was given the option to end or extend this incentive based on several factors specified in the law.

The dual fuel credit has not worked as Congress intended. Drivers of vehicles with the dual fuel option inevitably use conventional fuels, because outlets for alternative fuels are few and the fuels can be expensive. NHTSA decided⁸³ nonetheless in February 2004⁸⁴ to extend the dual fuel incentive, even though the government’s own analysis, confirmed in other studies, estimates that the result of extending the dual fuel incentive will be to *increase* petroleum consumption and emission of greenhouse gases. Projections are that the increase will swallow entirely the oil savings from the administration’s recent decision to require a modest hike in fuel economy standards of 1.5 mpg by 2008.⁸⁵

Spinning Its Wheels: Items Withdrawn

NHTSA continued this year to withdraw items from its agenda. The 13 items withdrawn during the last year bring NHTSA’s total withdrawals during this administration up to 31, of which 23 were proposed by the Clinton administration, two were proposed by the Bush I administration, and two had been on the agenda since the Reagan administration.⁸⁶ Although the

82. Pub. L. No. 100-494, 102 Stat. 2441.

83. See RIN 2127-AI41 (Automotive Fuel Economy Manufacturing Incentive for Alternative Fuel Vehicles).

84. See Incentives for Alternative Fueled Vehicles, 69 Fed. Reg. 7,689 (Feb. 19, 2004).

85. See Public Citizen’s comments on the dual fuel rule at <<http://www.citizen.org/autosafety/fuelecon/nhtsacafe/articles.cfm?ID=8775>> and comments by the Center for Auto Safety at <<http://www.autosafety.org/article.php?scid=77&did=833>>.

86. More details are available in the chart of NHTSA’s withdrawn items, available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>. The two Bush I items were RINs 2127-AB79 (Procedures for Considering Environmental Impacts) and -AC66 (Brake Lining), and the two Reagan items

withdrawals from the last year are not particularly troublesome, two of the rationales for them do suggest larger problems.

Considering in a Different Context

Some rules were terminated as distinct rulemaking enterprises because NHTSA opted to consider the item “in the context of” some other rulemaking. For example, its consideration of the use of 6-year-old dummies in static out-of-position tests was integrated into advanced air bag rulemaking, which NHTSA actually completed last year.⁸⁷ This kind of integration is not necessarily suspect.

It can, however, be an excuse for delay. Several rulemakings related to lighting, including one addressing problems of glare with daytime running lights, were withdrawn from the agenda because, as NHTSA explained, the agency had received a petition from an automaker seeking a rule mandating daytime running lamps and decided to consider other lighting issues in the context of reviewing that petition.⁸⁸ Issues of glare from current daytime running lamps could, however, be a segregable issue, quite distinct from whether auto safety would be improved by an across-the-board requirement of daytime running lamps.

Waiting for More Research

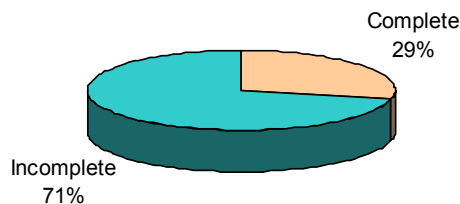
NHTSA explained two of this year’s withdrawals (or three total during this administration) as resulting from the agency’s wish to complete more research.⁸⁹ This explanation can be sensible, especially when there is new

were RINs 2127-AA03 (Crashworthiness Ratings) and -AA44 (Flammability of Interior Materials—School Buses).

87. See RIN 2127-AI71 (Static Out-of-Position Test Requirements at S23 Using 6-Year-Old Dummy).

88. See RINs 2127-AG86 (Glare Reduction from Daytime Running Lamps), -AG87 (Administrative Rewrite for Headlamp Requirements), & -AI62 (Daytime Running Lamps Intensity Reduction Phase II).

89. See RINs 2127-AG49 (Seat Belt Positioning Devices), -AG92 (Motorcycle Mounted Reflex Reflector Heights), & -AH50 (Ejection Mitigation Using Advanced Glazing).

Figure 11**NHTSA Benchmarks Listed Fall 2003
To Be Completed Spring 2004**

research from a credible, non-industry-funded and neutral scientist suggesting the agency needs to take a hard look at its current position. It can also, however, be an excuse for interminable delay. There can always be more research, but at some point the evidence of urgent problems can be so overwhelming that the better course of action is to issue a rule to be refined as further research becomes available. As a federal court recently reprimanded another Department of Transportation agency, “Regulators by nature work under conditions of serious uncertainty, and regulation would be at an end if uncertainty alone were an excuse to ignore a congressional command”⁹⁰

Stuck in Neutral: Continued Inaction

NHTSA’s record even for just the last six months shows a pattern of inaction. NHTSA failed to achieve fully 71 percent of the benchmarks announced in the December agenda that were due to be completed by June 2004.⁹¹ The pattern for the last six months is consistent with NHTSA’s pattern of failure since the Bush administration took office. Of the 85 items

90. *Public Citizen v. Federal Motor Carrier Safety Admin.*, 374 F.3d 1209, 1221 (D.C. Cir. 2004).

91. For more details on our analysis of agency benchmarks, see page 15 *supra*.

still on the NHTSA agenda when the Bush administration took office, 23 were abandoned and 31 still linger uncompleted. Although 21 uncompleted items have been added to the agenda in the wake of the withdrawn items, only three are economically significant. Two of those are essentially aspects of a single rulemaking, which was required in the wake of a federal court's rejection of a previous rule. The other potential rulemaking shows signs of being a rollback of current safeguards. Neither bodes well for auto safety.

Tire Pressure Monitoring Systems

The entry for tire pressure monitoring systems (TPMS)⁹² should look familiar, because NHTSA already addressed TPMS in past agendas and completed the item.⁹³ NHTSA was required by law to issue rules designed to alert drivers when their tire pressure becomes dangerously low. NHTSA decided to allow manufacturers to choose between installing a "direct" system, which relies on a pressure sensor in each tire that could alert the driver of an under-inflated tire through a dashboard monitor, and a less reliable yet cheaper "indirect" system, which works with anti-lock brakes to measure the rotational difference between the tires, determining whether the speed is slower for one tire compared to the others.

NHTSA had originally intended to require direct tire pressure monitoring systems to be installed in all vehicles by 2007, which NHTSA estimated would avert 10,271 injuries and 141 fatalities a year, compared to 5,000 injuries and 70 fatalities averted by indirect systems. OIRA returned the rule to NHTSA because OIRA Administrator John Graham insisted a standard allowing indirect systems would actually produce greater safety benefits overall as an incentive for manufacturers to install anti-lock brakes, which are necessary for an indirect system to work.⁹⁴

92. See RIN 2127-AJ23 (Tire Pressure Monitoring System).

93. See RIN 2127-AI33 (Tire Pressure Monitoring System).

94. See OMB Watch, "NHTSA Issues Weakened Tire Pressure Monitoring Rule," available online at <<http://www.ombwatch.org/article/articleview/805>>.

NHTSA's first attempt at a TPMS rule was vacated by a federal court.⁹⁵ NHTSA added an agenda entry to note its compliance with the court's order to remove that rule from the administrative code and start over.⁹⁶ A new agenda entry now reflects NHTSA's second pass at a rule, although the current evidence is that this new rule is going nowhere fast. A motion by Public Citizen to enforce the court's prior judgment is now pending in the Second Circuit. Amazingly, even though the TPMS rule is now long past its original statutory deadline and NHTSA's rulemaking is now under court order, NHTSA is apparently once again delaying the rule in order to appease OIRA and its demand for industry-friendly economics analysis. In response to Public Citizen's motion to enforce the judgment, NHTSA actually claimed that this delay was evidence of the agency's efforts to comply.⁹⁷

Fuel Economy: Structural Reform

Another item on NHTSA's agenda threatens to undermine the corporate average fuel economy (CAFE) program. The CAFE standards, enacted in 1975, dictate the average fuel usage, calculated in miles per gallon (mpg), that passenger cars and light-duty trucks sold in the United States must attain. According to the National Environmental Trust, the law has been remarkably effective in that the average fuel economy of new passenger cars has roughly doubled from 14 mpg in the 1970s to 28 mpg today. Gasoline consumption is down roughly 118 million gallons per day from where it would have been in the absence of CAFE standards; that amount is equal to approximately 913 million barrels of oil per year, or about the total imported annually from the Persian Gulf. New cars purchased in 1999 use 3.7 billion fewer gallons of gasoline per year than they would in the absence of CAFE standards. The only way to produce a dramatic savings in oil consumption, as

95. See *Public Citizen v. Mineta*, 340 F.3d 39 (2d Cir. 2003).

96. See RIN 2127-AJ22 (Tire Pressure Monitoring System; Vacation of Standard).

97. See Resp. to Pet'rs' Mot. to Enforce J., *Public Citizen v. Mineta*, No. 02-4237 (2d Cir. Aug. 6, 2004) ("The most recent report shows that the draft NPRM was sent to OMB on July 1, 2004. See Report on DOT Significant Rulemakings, July 2004, available at <http://regs.dot.gov/rulemakings/200407/nhtsa.htm>. The schedule has been updated, and the report indicates that the new dates reflect "[u]nanticipated issues requiring further analysis."").

witnessed in the 1970s and 80s, is to reinvigorate the CAFE program by setting higher fuel efficiency standards.⁹⁸

With renewed calls for energy independence and the popularity of gas-guzzling sport utility vehicles, the sensible course of action would be to improve CAFE standards by raising the current low standard for the light truck category in which SUVs are regulated. The CAFE structural reform item added to NHTSA's agenda⁹⁹ does propose overhauling fuel economy standards as they apply to the light truck category, but it does not propose actually improving vehicle fuel economy. Instead, NHTSA's *Federal Register* notice incorporates long-held beliefs of OIRA Administrator John Graham, among them that fuel economy standards somehow lead to a dangerous proliferation of small cars.¹⁰⁰ Graham spent years at the industry-funded think tank he founded¹⁰¹ promoting the fallacious claim that CAFE induces weight reductions that are dangerous, contrary to studies demonstrating that weight reductions actually reduce highway fatalities and that aggressive vehicle design is a more significant safety factor than vehicle weight. The most likely projection is that this rulemaking will weaken fuel economy standards and endanger motorists in smaller vehicles hit by larger, heavier vehicles.¹⁰²

98. For more information on fuel economy, see the Center for Auto Safety fuel economy page on-line at <<http://www.autosafety.org/fueleconomy.php>>; National Environmental Trust, "The Facts About Raising Auto Fuel Efficiency," available on-line at <<http://www.net.org/proactive/newsroom/release.html?id=27517>>; Public Citizen, "Corporate Average Fuel Economy," on-line at <<http://www.citizen.org/autosafety/fuelecon/>>.

99. See RINs 2127-AJ17 (Reforming the Automobile Fuel Economy Standards Program) & -AJ26 (Reforming the Automobile Fuel Economy Standards Program; Request for Product Plan Information).

100. See *Reforming the Automobile Fuel Economy Standards Program*, 68 Fed. Reg. 74,908 (Dec. 29, 2003).

101. For more detail on Graham's past at the industry-funded think tank he founded and headquartered in Harvard's public health school, see Laura MacCleery, Public Citizen, *Safeguards at Risk: John Graham and Corporate America's Back Door to the Bush White House* (2001) (available on-line at <<http://www.citizen.org/documents/grahamrpt.pdf>>).

102. A Freedom of Information request by Public Citizen has revealed that Graham was foremost among a cadre of top-level White House and agency officials who have been meeting in secret since at least the summer of 2001 to work on this proposed structural overhaul. OMB has refused to answer a follow-up FOIA request, and a lawsuit is now pending. See OMB Watch, "OMB Role in Fuel Economy Change Exposed," available on-line at <<http://www.ombwatch.org/article/articleview/2207>>.

OSHA: Sleeping on the Job

The Occupational Safety and Health Administration (OSHA) continued to be the black hole of government during the last year. The last two agendas reflect only three total completed items, of which one was a rollback of current protections while another was not even a rulemaking. OSHA continued to withdraw crucial workplace health and safety priorities or allow them to languish on the agenda. After withdrawing most of its identified priorities in December 2001 with one repeated excuse—“OSHA is withdrawing this entry from the agenda at this time due to resource constraints and other priorities”—OSHA has failed to identify the “other priorities” that warrant abandoning recognized workplace health and safety problems.

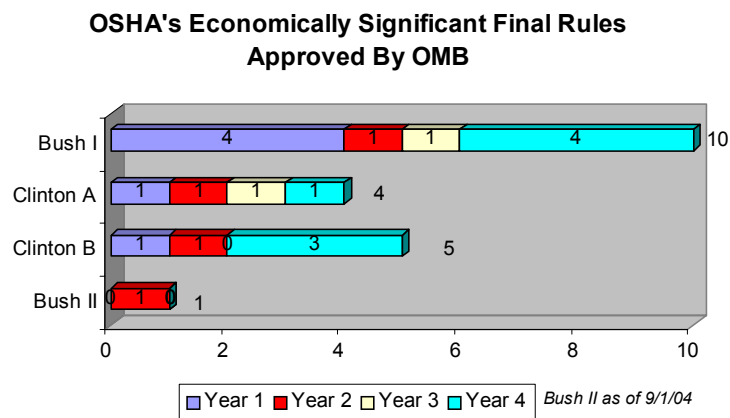
Just Showing Up: Items Completed

OSHA’s record of completed actions is essentially empty. Over the last year, OSHA can only point to three items that were completed. One of these was merely a review of existing regulations for their economic consequences for small businesses.¹⁰³ Of the two that can be treated as rulemaking endeavors, one only codified an exemption from a commercial diving operation standard that until then OSHA had been routinely granting to recreational diving operators upon request.¹⁰⁴

103. Of the three completed items—RINs 1218-AB97 (Commercial Diving Operations: Revision), -AC06 (Occupational Injury and Illness Recording and Reporting Requirements), and -AC03 (Presence Sensing Device Initiation of Mechanical Power Presses (Section 610 Review))—the last item reflects only that OSHA conducted an analysis of an already-existing rule in accordance with the Regulatory Flexibility Act, 5 U.S.C. § 610(a), which requires periodic re-examination of rules that have a significant economic impact on “small businesses.”

Although those who follow workplace health and safety issues generally refer to rulemakings by their agency docket number, those numbers are not used in the Unified Agenda. (Some agenda items actually track potential rulemakings for which the agency has not yet opened a docket, in addition to activities such as research projects for which docket numbers are occasionally inapposite.) In order to facilitate cross-references between the Unified Agenda, this analysis, and the related tracking chart and table of withdrawn items (available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>), we are adopting the agenda practice of referring to items by their RINs.

104. See RIN 1218-AB97 (Commercial Diving Operations: Revision). See also Commercial Diving Operations, 69 Fed. Reg. 7,351 (Feb. 17, 2004).

Figure 12

The last one does not address a problem but, instead, actually sweeps a problem under the rug. Musculoskeletal disorders are a significant workplace risk: there were approximately 1.6 million MSDs in 2002, of which 500,000 were so serious that workers had to miss time from their jobs. OSHA decided on June 30, 2003¹⁰⁵ not to address workplace hazards that can lead to these disorders but, instead, to eliminate the requirement that employers report MSDs as a separate item when reporting workplace health and safety statistics.¹⁰⁶ The disorders will not disappear, but our knowledge of them will.

This inadequate output from the last year is only the latest evidence of OSHA's unprecedented failure to protect American workers. As Figure 12 dramatically illustrates, OSHA has produced far fewer important workplace health and safety protections than either the Clinton or Bush I administrations.¹⁰⁷ In fact, that chart even gives the Bush II OSHA more credit than it actually deserves: although OSHA did submit one final rule for White House approval that was initially designated as economically significant, the final published rule was not so designated. During the entirety of this

¹⁰⁵. See Occupational Injury and Illness Recording and Reporting Requirements, 68 Fed. Reg. 38,601 (June 30, 2003).

¹⁰⁶. See RIN 1218-AC06 (Occupational Injury and Illness Recording Reporting Requirements).

¹⁰⁷. See pages 20-21 *supra* (explaining the source—and limitations—of OIRA review data).

administration, OSHA has failed to produce any economically significant protections of American workers.

Shirking Responsibility: Items Withdrawn

OSHA cleared away most items that would address major workplace health and safety issues back in its fall 2001 agenda, when the agency withdrew 16 items—a full third of the items then on the agenda. OSHA targeted two more items for removal in the last year, bringing the total number of withdrawals to 24 (of which three date back to the Reagan administration, while two date back to Bush I, and the remaining 19 were proposed in the Clinton administration).¹⁰⁸ Joining the graveyard of needed protections this year are two items that further this larger trend of failing to protect workers.

Tuberculosis

The most dramatic is OSHA's decision to abandon work on a standard for occupational exposure to tuberculosis.¹⁰⁹ Health care workers, especially those in emergency rooms and health clinics who serve homeless and mentally ill patients, are particularly at risk. After a mid-1980s surge in TB cases, the Centers for Disease Control and Prevention (CDC) suggested guidelines for reducing the exposure and spread of tuberculosis, including occupational exposure, and OSHA followed suit in 1997 with a proposed rule that mirrored many of the CDC's guidelines.¹¹⁰

Even though there were still 15,000 reported cases of TB in 2002, OSHA decided to withdraw the TB rule from the June 2004 agenda, explaining that adoption of the CDC's guidelines were in part responsible for a steady decline of TB and, accordingly, the risk of occupational exposure to

108. The three Reagan-era items are RINs 1218-AA68 (Scaffolds in Shipyards), 1218-AA70 (Access and Egress in Shipyards), and -AA84 (Glycol Ethers). The two Bush I items are RINs 1218-AB27 (Accreditation of Training Programs for HAZWOPER) and -AB54 (PELs for Air Contaminants). Details on the remaining Clinton-era items are available on the chart of OSHA's withdrawn items, available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>.

109. See RIN 1218-AB46 (Occupational Exposure to Tuberculosis).

110. See Occupational Exposure to Tuberculosis, 62 Fed. Reg. 54,160 (Oct. 17, 1997).

it. Because the CDC guidelines are only unenforceable suggestions, however, they have not been implemented evenly. According to a 1997 AFSCME study cited by OSHA, a survey of correctional facilities found “a wide variation of adherence to CDC guidelines from departments that had instituted rigorous programs throughout prison systems to those that had done very little.”¹¹¹ In fact, the decline of TB has reflected that same unevenness; as pointed out by the SEIU and others, the uneven implementation of the CDC guidelines can be seen in the geographic variation in the decline of TB cases.¹¹²

The virtue of an across-the-board regulation is that the benefits of TB prevention efforts would be widely shared across the industry, and workers would not depend on the whims of their employers. A rule is *fair*; one standard applies to all workers, although generous employers will always remain free to exceed the universal minimum. The decision to abandon a fair TB rule is only the latest example of OSHA withdrawing an item in favor of nonmandatory, voluntary guidelines.¹¹³

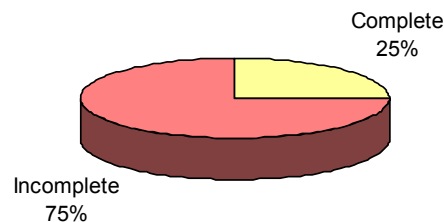
Glycol Ethers

OSHA set standards for worker exposure to ethylene glycol ethers back in 1971, based on evidence of toxic effects on the blood, kidney, liver, and central nervous system. Evidence emerged from animal tests that linked glycol ethers, used in manufacturing semiconductor chips, to reproductive damage and birth defects. Several lawsuits have been filed against chip manufacturers based on exposure to glycol ethers in solvents used in the manufacturing process. Arguing that glycol ethers have been phased out or are now “virtually limited” to settings in which exposure levels ten years ago were already at or below the permissible exposure level (PEL) of the proposed rule, OSHA declined to lock in that PEL with a rule and instead withdrew the item

111. 68 Fed. Reg. 75,768, 75,772 (Dec. 31, 2003).

112. See Nat’l Ctr. for HIV, STD, & TB Prev., Centers for Disease Control & Prev., “Reported Tuberculosis in the United States, 2002,” Tbl.17 (available on the web at <<http://www.cdc.gov/nchstp/tb/surv/surv2002/PDF/T17.pdf>> & <<http://www.cdc.gov/nchstp/tb/surv/surv2002/tables/T17.htm>>).

113. See RINs 1218-AB27 (Accreditation of Training Programs for HAZWOPER), -AB41 (Injury and Illness Prevention (Safety and Health Programs)), & -AB58 (Metalworking Fluids).

Figure 13**OSHA Benchmarks Listed Fall 2003
To Be Completed Spring 2004**

altogether from its June 2004 agenda, after it had lingered on the agenda since April 1987.¹¹⁴

Sleeping at the Desk: Continued Inaction

Having removed yet more items from its priority list, OSHA still allows crucial safeguards to languish on its agenda. In the six-month span between the December 2003 and June 2004 editions of the Unified Agenda, OSHA failed to achieve 75 percent of the major benchmarks due for completion in that time.¹¹⁵

The record of inaction from the last six months actually reflects a larger pattern of inaction since the Bush administration took office. Two of the 15 lingering agenda items this administration inherited from prior

114. See RIN 1218-AA84 (Glycol Ethers: 2—Methoxyethanol, 2—Ethoxyethanol, and Their Acetates: Protecting Reproductive Health).

115. For more details on our analysis of agency benchmarks, see page 15 *supra*.

administrations have been awaiting action since the Bush I administration.¹¹⁶ These 15 languishing items would address workplace health and safety issues ranging from hearing loss in construction workers to general working conditions for shipyard employment. Three are particularly troubling.

Payment for Personal Protective Equipment

Some personal protective equipment, such as fall arrest systems, safety shoes, and protective gloves, are vital safety measures that workers must currently purchase on their own. A rule first proposed back in March 1999 would have required employers to pay for these items, but it has since languished on OSHA's regulatory agenda for most of the past four years.¹¹⁷ OSHA has recently reopened the rule for yet more public comments, four years after the public had ample opportunity for commenting. Labor groups criticize this move as only further delaying action while giving the appearance that the agency is working on the rule.¹¹⁸

Occupational Exposure to Hexavalent Chromium

OSHA estimates that approximately one million workers are exposed to hexavalent chromium, which is used in chrome plating, stainless steel welding, and the production of chromate pigments and dyes. Every year, hundreds of workers die prematurely of lung cancer because of that exposure. A 1995 OSHA study found that as many as 34 percent of workers exposed to hexavalent chromium at OSHA's current exposure limit for eight hours a day over 45 years could contract lung cancer. Public Citizen and a labor group successfully sued OSHA and won a court order for OSHA to issue a new, safer

116. See RINs 1218-AA56 (Longshoring and Marine Terminals) (first added in November 1992 agenda) & -AB80 (Walking Working Surfaces and Personal Fall Protection Systems (1910) (Slips, Trips, and Fall Prevention)) (first notice published in April 1990). For information on the remaining thirteen Clinton-era items, consult the chart of OSHA's withdrawn items available on-line at <<http://www.ombwatch.org/regs/patternoffailure>>.

117. See RIN 1218-AB77 (Employer Payment for Personal Protective Equipment).

118. See OMB Watch, "OSHA Delays Worker Safety Action, Reopens PPE Rule for Comment," available on-line at <<http://www.ombwatch.org/article/articleview/2307>>.

worker exposure limit for hexavalent chromium. Although OSHA's rule¹¹⁹ has been languishing on the agenda in the proposed or prerule stage since April 1994, the agency is now required by court order to publish a notice of proposed rulemaking by October of 2004.¹²⁰

Protection from Silicosis

According to the American Public Health Association, there were 13,744 deaths in the United States between 1968 and 1990 with silicosis as a primary or contributing cause. Silicosis is a fatal lung disease caused by inhaling silica dust, the most common mineral in the earth's surface.¹²¹ Cases of silicosis still appear in rock drill operators working on surface mines or highways, construction workers who use sand in abrasive blasting, and foundry workers who make sand castings. Silicosis is entirely preventable with the implementation of conventional public health methods including the use of less hazardous materials, dust suppression techniques, improved ventilation, and respirator use, but underuse of these techniques means that silicosis remains a problem. The National Institute for Occupational Safety and Health has recommended exposure limits that are much lower than those currently existing.¹²² An OSHA rule¹²³ on this issue has languished in the prerule or proposed stage on the agenda since October 1997, and no action has been taken to finalize the rule.

119. See RIN 1218-AB45 (Occupational Exposure to Hexavalent Chromium).

120. See *Public Citizen Health Res. Grp. v. Chao*, No. 02-1611, 2003 WL 22158985 (3d Cir. April 2, 2003) (order); *Public Citizen Health Res. Grp. v. Chao*, 314 F.3d 143 (3d Cir. 2002) (decision).

121. A literary account documenting a silicosis crisis from the 1930s is available in Muriel Rukeyser, "The Book of the Dead," *U.S.* 1 (1938).

122. See *Special Interest Takeover*, *supra* note 3, at 66-67.

123. See RIN 1218-AB70 (Occupational Exposure to Crystalline Silica).

Conclusion

From Special Interest Takeover to Public Interest Take-Back

OMB Watch believes—as do overwhelming majorities of the American public—that the federal government has an important role to play in serving the public interest.¹²⁴ We believe specifically that the government should use regulatory policy to promote social justice and protect the public health, safety, civil rights, and environment. Whether the goal is protecting infants and pregnant women from exposure to mercury and other toxins, ensuring that the nation's blood supply is secure, reducing the risk of fatal accidents in the event of a car crash, or shielding workers from exposure to dangerous carcinogens, the federal government is uniquely positioned to marshal the nation's resources in the service of the public welfare. The Bush administration's record is a breathtaking abdication of that responsibility, and its hostility to regulatory protections is unprecedented in its breadth and depth.

To turn this problem around—to move from a special interest takeover to a public interest take-back—requires a complete overhaul of the administration's approach to regulatory policy. The single consistent theme in this administration's regulatory record, both in the last year and during the entirety of this administration to date, is a tendency to put special industry interests above the public interest. The public that overwhelmingly supports the government's role in protecting the public must speak back to the administration and Congress to demand the public safeguards we all need. One good vehicle is an automated form letter made available by Citizens for Sensible Safeguards, a coalition of public interest organizations across the country committed to reasonable protections of the public welfare, on the coalition's website at <<http://www.sensiblesafeguards.org/speakout.phtml>>.

The administration could also take measures to ensure that the public receives the information it needs to hold the agencies accountable for their

¹²⁴. See Harris Survey, *supra* note 1.

regulatory policies. The semiannual publication of the Unified Agenda is a good opportunity to provide such information, but not all agencies are making the best use of these agendas. For example, some agencies, in particular the Environmental Protection Agency and the Food and Drug Administration, fail to explain their decisions to terminate work on agenda items. A few simple reforms could make it easier for the public to use the Unified Agenda to hold agencies accountable.

- Agencies should be required to disentangle rulemakings from the other items—in particular, petitions for reconsideration and section 610 reviews—that appear on the Unified Agenda.
- Agencies should begin to log withdrawn items separately from completed actions. The decision to abandon work altogether on an item is so different from the issuance of a final rule that the two do not belong together under the same heading, much less as though all were “completed.”
- Agencies should be required to explain, in clear and accessible language, the problems to be addressed by any item on the agenda and the reasons for any withdrawals. There are too many agenda entries with only dry, technical explanations for launching a rulemaking initiative that do not identify the public need to be served by a rule. Likewise, there are too many agenda entries that were placed on the Unified Agenda with compelling statements of the need to be served but were subsequently dropped without any explanation.
- Agencies should do a much better job of listing *Federal Register* citations related to agenda items. The Unified Agenda cannot contain all information relevant to a particular agenda item, and a wealth of additional information is available in the agencies’ notices published in the *Federal Register*. The agendas do have a subsection reserved for listing these citations, but the agencies do a haphazard job of listing them. Although

it is possible to use RINs as a search term to retrieve these notices from a commercial database such as Westlaw or Lexis-Nexis, the many members of the public without access to such expensive services should be provided the citations they can take to any public law library.

- The Unified Agenda should begin to cross-reference entries with agency docket numbers. These docket numbers are the single most important tool for discussing specific rulemakings with advocacy groups and filing advocacy comments with the agencies. Armed with docket numbers, the public can start with the Unified Agenda and move directly to an advocacy posture.

With an administration that actually responds to the public's call for safeguards and with an improved Unified Agenda that actually helps the public hold agencies accountable, perhaps then the agency agendas will cease being do-nothing lists and become the to-do lists that the administration claims they are.