

ENFORCEMENT Agency regulatory analysis is a creature of the executive branch that has its roots in Richard Nixon’s “Quality of Life” review process, and that is now embodied in EO 12,866. Expanding its scope to include some performance management practices is completely within the president’s power. OIRA is currently charged with checking that agencies have complied with the executive order and it could also be tasked with performance management requirements.

The executive order, however, does not apply to independent commissions. That said, the president could appoint only commissioners and chairpersons that agree with him on the importance of performance management. Additionally, GPRA does apply to independent commissions and the OMB is tasked with interpreting the act and giving agencies and com-

missions compliance guidance. The president could try to make independent agencies engage in some regulatory review by inserting a requirement in Circular A-11. However, there is no procedural check like the one OIRA provides for executive agency regulatory analysis. It would be up to Congress to enforce a requirement.

CONCLUSION Effective performance management of regulatory agencies requires regulatory analysis. Conversely, regulatory analysis is nothing more than sound strategic planning and performance management applied to regulation. The changes we suggest would go a long way toward integrating and strengthening performance management and regulatory analysis in regulatory agencies. **R**

Doctors for Gun Control

BY ROBERT A. LEVY

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Just weeks after the Supreme Court issued its blockbuster opinion in the landmark Second Amendment case *District of Columbia v. Heller*, two prominent medical journals were in print with an editorial and two articles asserting that guns at home are a major public health problem.

First off the press was the July 31, 2008, *New England Journal of Medicine* editorial “Guns and Health,” citing statistics from the Centers for Disease Control and Prevention on the number of injuries and deaths from handgun use. Five weeks later, the same journal published “Guns and Suicides in the United States,” by the Harvard School of Public Health’s Matthew Miller and David Hemenway, summarizing studies purporting to establish a direct relationship between suicides and household gun ownership. Four weeks later, Georgetown University law professor Lawrence Gostin expanded on the guns-cause-violence theme in “The Right to Bear Arms,” a brief paper on gun control law and politics that appeared in *JAMA: The Journal of the American Medical Association*.

The articles and editorial raise two important questions: Is there persuasive empirical data that lawful gun ownership makes the public less safe? If so, would public safety be enhanced by tighter gun

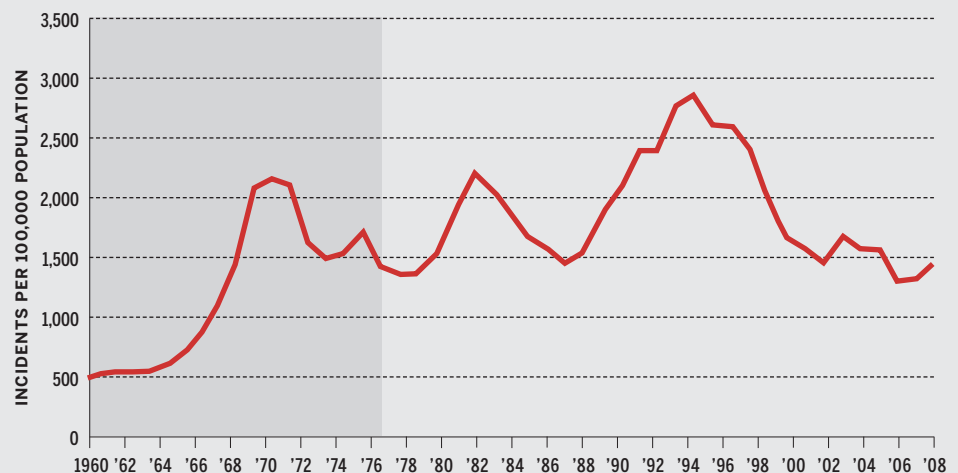
controls? There is a rich academic literature examining those questions, and the literature indicates “No” for both questions.

Disappointingly, neither the *NEJM* nor *JAMA* wants to discuss those peer-reviewed studies. Indeed, when I offered to write a short article in response to the *NEJM* editorial, my offer was declined. When I volunteered to convert the short article into an even shorter letter-to-the-editor, that too was declined. Other lawyers have written for the *NEJM*, but none represented Mr. Heller before the Supreme Court as I did. Perhaps viewpoint discrimination explains the one-sided coverage of this issue by both the *NEJM* and *JAMA*. So I will share a few of those counter-arguments here.

Figure 1

District of Columbia Violent Crime Rate

Gun ban implemented September 24, 1976



SOURCE: FBI, Uniform Crime Reports as prepared by the National Archive of Criminal Justice Data

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GUNS AND SAFETY The *NEJM*'s editors cite, with justifiable concern, CDC data on handgun-related injuries and deaths. But the editors conveniently ignore a comprehensive 2003 CDC report on the efficacy of firearms and ammunition bans, restrictions on acquisition, waiting periods, registration, licensing, child access prevention laws, and zero tolerance laws. The report's conclusion: There is "insufficient evidence to determine the effectiveness of any of the firearms laws or combinations of laws reviewed on violent outcomes."

"Research has shown," the *NEJM* editorial claims, "that fewer restrictions on handguns will result in a substantial increase in injury and death." To the contrary: a 2004 National Academy of Sciences review of 253 journal articles, 99 books, and 43 government publications evaluating 80 gun-control measures concluded that "existing research studies ... do not credibly demonstrate a causal relationship between the ownership of firearms and the causes or prevention of criminal violence or suicide."

The *NEJM* editorial writer does offer one citation to specific data on the relationship between guns and public health: a 1991 *NEJM* article ostensibly documenting a 25 percent decline in gun-related homicides and suicides immediately after the District of Columbia enacted its 1976 gun ban. But that study has been discredited for its biased selection of comparable jurisdictions, failure to adjust for D.C.'s declining population, disregard of other explanatory variables, and selective choice of time periods. Further, a 1996 paper in the *Law and Society Review* found that if the study, which ended in 1987, had been extended by just two years, the observed decline would have disappeared.

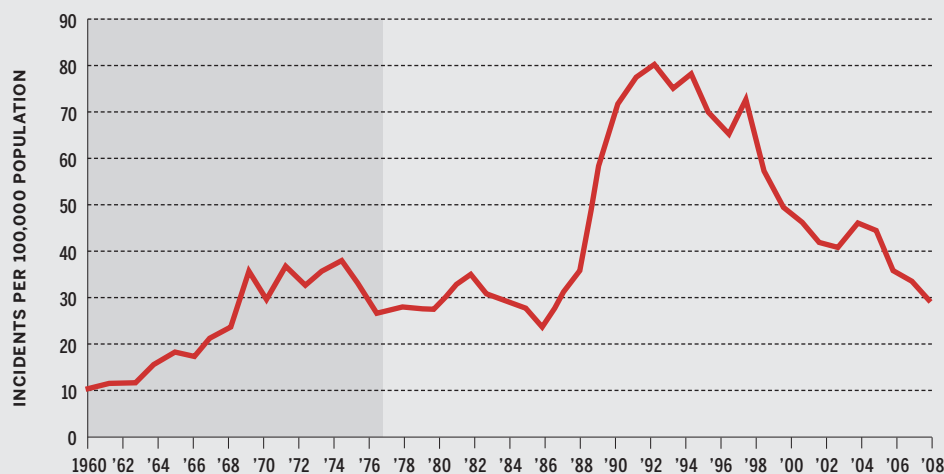
Interestingly, the District exempted pre-existing handguns from its 1976 ban. If handgun availability were positively linked to suicides, one would expect suicides to decline progressively as owners gradually sold, discarded, or removed pre-1976 guns from the city. But the suicide rate was the same in 1998 (7.6 per 100,000) as it was in 1981, and ranged from 4.9 to 11.8 during the intervening period. The decline in suicides reported in the 1991 *NEJM* article was a temporary, random phenomenon.

Looking at suicide data cross-sectionally — e.g., comparing states having the highest rates of gun ownership with states having the lowest rates — Miller and Hemenway conclude in their *NEJM* article that high gun ownership goes hand-in-hand with high rates of firearm suicide and overall suicide. But numerous studies, not cited in their article, have concluded otherwise. Florida State University criminologist Gary Kleck, for example, cites studies based on local, national, and international data showing that nations with fewer guns do not have fewer suicides. New York University law professor James B.

Figure 2

District of Columbia Homicide Rate

Gun ban implemented September 24, 1976



SOURCE: FBI, Uniform Crime Reports as prepared by the National Archive of Criminal Justice Data

Jacobs confirms that the U.S. suicide rate is equal to the average for industrialized nations, despite America's higher rate of gun ownership.

Correlation studies between suicide rates and gun ownership are further complicated by confounding variables — including differences in the percentages of single-parent households, the portion of the population that hunts, and the preponderance of selected racial and ethnic groups (most importantly, African-Americans, who have a much lower suicide rate than whites). The association of confounding variables with both suicide and gun ownership can make it appear that suicide and gun ownership are themselves correlated, when they are not.

REGULATION AND SAFETY Even if it could be shown that suicides, crime, or accidents increase as gun ownership increases, the preventive or remedial effect of gun control must also be demonstrated. On that question, the *NEJM* editorial simply asserts that the problem of firearm injuries "seems certain to be exacerbated with less handgun regulation." That is a gross and careless overstatement. There is little reliable evidence — much less certainty — of a statistically significant inverse relationship between handgun regulations and firearms injuries. In fact, much of the evidence points to a direct relationship: more regulations limit the deterrent effect of defensive firearms and lead, therefore, to more injuries.

Washington, D.C., affords a crystalline example: Since implementation of the District's ban, the city's murder rate has fallen only once below what it was in 1976. The overall violent crime rate in D.C. dropped below its 1976 level in only four years during the three ensuing decades. Most distressing, the District has ranked first or second in yearly murders 15 times since the ban has been in place. FBI data for 2006 indicate that the District's murder rate was more than five times higher than the national average, and more than double the rate in comparably sized cities — none of which had gun laws as

restrictive as the District's.

Perhaps recognizing that crime data provide compelling support for the proposition that gun control doesn't work, Gostin's article in *JAMA* highlights accident statistics. "A gun in the home is far more likely to be involved in killing a family member than an intruder," insists Gostin. Even if true, the point is irrelevant. The benefit of a gun in the home is not to shoot bad guys; that rarely happens. The real benefit is the deterrent effect on the commission of crime. Peer-reviewed studies indicate that guns are used defensively — almost always brandished, not fired — five times more often than they are involved in violent acts. More important, the *JAMA* article does not consider the countless instances of violent acts *not* undertaken because the potential victims might be able to defend themselves with suitable firearms.

BURDEN OF PROOF One final point: A few seemingly sophisticated statistical analyses suggest that more firearms mean more gun violence, and more gun regulations will alleviate the problem. But many more analyses suggest the opposite. How then should a court, considering the tradeoff between public health and the Second Amendment, weigh the evidence? Do the regulators or the firearms rights advocates have the burden of proof? That is a legal, not social science, question.

When courts review regulations to determine whether they pass constitutional muster, judges must first decide how rigorously they will scrutinize enactments of the legislative branch. Under so-called rational basis scrutiny, courts typically rubber-stamp whatever the legislature passes as long as the judge can conceive of a legitimate justification for the law.

Challengers face a heavy burden in showing that no rational basis exists. At the other extreme is "strict scrutiny," whereby courts will demand proof from government that state interests are compelling and the regulation is no more restrictive than necessary to attain the desired goal.

In *District of Columbia v. Heller*, the Supreme Court categorically rejected rational basis scrutiny for the review of firearms laws. Something higher is demanded, said Justice Antonin Scalia, when an express constitutional right is at issue; the District's ban on all functional firearms in the home was unconstitutional "under any of the standards of scrutiny the Court has applied to enumerated constitutional rights." Although the Court did not explicitly adopt strict scrutiny, it certainly moved in that direction.

It is clear, post-*Heller*, that government has the burden of proof in justifying gun regulations that might infringe on Second Amendment rights. It is equally clear — notwithstanding the predisposition of the *NEJM* and *JAMA* — that the regulators have not met their burden. **R**

Readings

- "A Reassessment of the D.C. Gun Law: Some Cautionary Notes on the Use of Interrupted Time Series Designs for Policy Impact Assessment," by Chester L. Britt, Gary Kleck, and David J. Bordua. *Law and Society Review*, Vol. 30 (1996).
- *Firearms and Violence: A Critical Review*, edited by Charles F. Wellford, John V. Pepper, and Carol V. Petrie. National Academy of Sciences, 2004.
- "First Reports Evaluating the Effectiveness of Strategies for Preventing Violence: Firearms Laws," by Robert A. Hahn, O. Bilukha, A. Crosby, et al. Centers for Disease Control and Prevention, October 3, 2003.

Harming Patients' Condition

BY HENRY I. MILLER

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One of the cornerstones of American medicine is the flexibility of physicians to prescribe drugs for "off-label" uses that have not yet been approved by the Food and Drug Administration. Instead, the prescriptions are based on doctors' reading of the medical literature and their own professional judgment. This "practice of medicine" traditionally has not been constrained by federal drug regulators. With the exception of certain "controlled substances" such as narcotics, drugs generally may be freely prescribed and advertised.

During the past several years, however, the increasingly risk-averse Congress and FDA have been gradually moving toward what amounts to "conditional" or limited approvals of new drugs that place various restrictions on their prescribing, distribution, sale, and advertising. At the same time,

they have imposed additional requirements for the demonstration of safety and efficacy in order to obtain even those limited approvals. That has delivered a devastating double-whammy to patients and has damaged one of the nation's most innovative and critical industries.

As a result, at a time when drug development should have been spurred by huge increases in research and development expenditures — which tripled to more than \$45 billion between 1995 and 2007 — and by the exploitation of numerous new technologies, drug approvals have actually dropped. The 19 approvals in 2007 were the lowest in 24 years, and 2008's figures are running behind last year's.

NO DRUGS, NO PROBLEMS Bringing a new drug to market now requires, on average, 12–15 years and costs more than \$1.2 billion in direct and indirect expenses. Several recent developments at the FDA will further increase the time and cost of drug development — bad news for the developers of

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