

Abstract

A White Paper Analysis of Marcia Angell's Boston Globe Column "High cost of me-too drugs"

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Introduction

Marcia Angell's "High cost of me-too drugs" column in the February 12, 2007 issue of The Boston Globe¹ contains numerous factual and contextual errors concerning the operations of Medicare, the Federal budget process, and the FDA, and has a fanatical tone that undermines its credibility. Rather than educate the public and promote progress toward solutions, her inaccuracies and slanted prose may inflame controversy over important issues.

Some specific problems with her statements are:

Medicare Does Not Directly Administer Medicare:

- ✓ Marcia Angell's description of Medicare Part D (the new outpatient prescription drug benefit) as not being administered by Medicare, "unlike **every other** part of the program," and her recommendation that Part D "should be treated like the rest of Medicare – **directly administered**" is based on a false premise.

The Center for Medicare and Medicaid Services (CMS) contracts out the administration of Medicare. It does not directly administer any parts of Medicare. Parts A and B, (also known as traditional Medicare) are administered by private entities that the government contracts with to pay hospitals, doctors and others that provide healthcare services or products to people with Medicare. Part C is administered by private healthcare organizations (such as managed care organizations and HMOs), that directly provide care for Medicare enrollees. Part D is administered by private plans known as Prescription Drug Plans, and the administrative structure for Medicare Part D is very close to the administration of Medicare Part C.

Medicare Does Not Negotiate Prices for Any Specific Clinical Goods or Services:

- ✓ Angell recommends that the new drug benefit should be "treated like the rest of Medicare...with negotiated prices." This reflects a misunderstanding of how Medicare sets payment rates for goods and services. Payments to clinicians and hospitals are done with specific fee schedules.

Medicare's Drug Benefit Isn't "Squeezing" Other Parts of Medicare:

Medicare's Drug Benefit Doesn't Have to be "Paid For" Every Year:

Medicare's Drug Benefit Is Costing Less than Expected:

- ✓ The assertion that the government will "have to squeeze other parts of Medicare to pay for" the prescription drug benefit is a broad misrepresentation of Medicare financing and the Federal budget process:
 - Congressional budget rules require that new entitlement programs, such as Medicare Part D, be "paid for" at the time they are created.

¹ http://www.boston.com/yourlife/health/diseases/articles/2007/02/12/high_cost_for_me_too_drugs

- The actual costs of Medicare’s Part D have been significantly less than expected when the legislation was signed into law:
 - Estimated costs to the government have declined by about 26%, and are projected to be \$136 billion less for 2007 to 2013. (See Figure 1)
 - Enrollee premiums have also been lower than expected.

“Me-Too” Drugs are Largely a Myth:

- ✓ Marcia Angell’s often-repeated claim that most new medicines are no better than old ones is based on a distortion of the FDA approval process in two ways:
 - She ignores the contribution made by FDA approved biologics.
 - Saying that “fully 80 of drugs approved in this decade are unlikely to be better than existing ones” represents not only a misunderstanding of the FDA approval process, but is also a flawed analysis of FDA’s data. Specifically, she disregards 37% of all priority approvals as unimportant because they are for new dosage forms, formulations, salts, or indications of existing medicines, rather than entirely new compounds. (See Figures 2 & 3)

Research is Driven by Revenues, Not by Magic Beans:

- ✓ Marcia Angell’s assertion that lower prices wouldn’t stifle research is an oft-repeated claim based upon the belief that faced with reduced gross incomes companies would cut other expenses while preserving research. But, that illogic doesn’t pass the laugh test.

Helping People is Terrible?

- ✓ As of January 2007, about 39 million Medicare beneficiaries have prescription drug coverage. This represents a significant increase in coverage compared with the period before the start of Medicare Part D: Now about 90% of beneficiaries have prescription drug coverage that is either through Medicare Part D or is equivalent to (or more generous than) what Medicare Part D plans are required to provide.

In 2006, 60% of Prescription Drug Plans have no deductible and 86% charge tiered co-payments for covered drugs rather than the standard benefit’s 25% coinsurance. Therefore, not surprisingly, few Medicare enrollees have chosen plans with the standard benefit package: At the beginning of 2007, 88.5% of enrollees in Medicare Prescription Drug Plans were in plans that had a benefit structure different from the standard benefit shown in Figure 4.

- ✓ Satisfaction with the new benefit is high. 42% of seniors had a favorable impression of the new Medicare drug benefit and 34% had an unfavorable impression. This same survey also found that 53% of seniors felt that the program was working well and shouldn’t be changed, versus 38% that felt it needed major changes (28%) or should be scrapped (10%).

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Figure 1

Cost Estimates for Medicare Part D: 2004 v. 2007

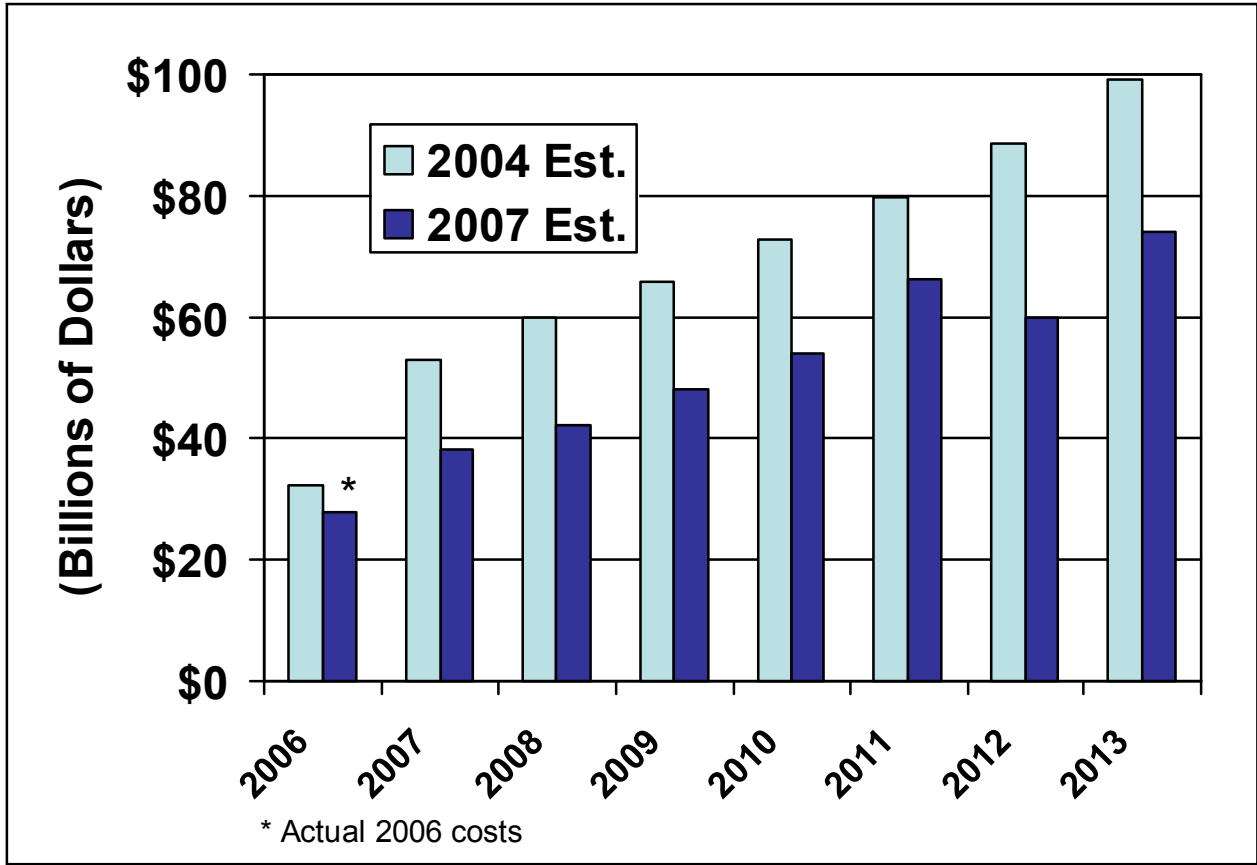


Figure 2
 Approvals of New Medicines by the FDA (1990-2006) According to Priority of Review and Type of Application

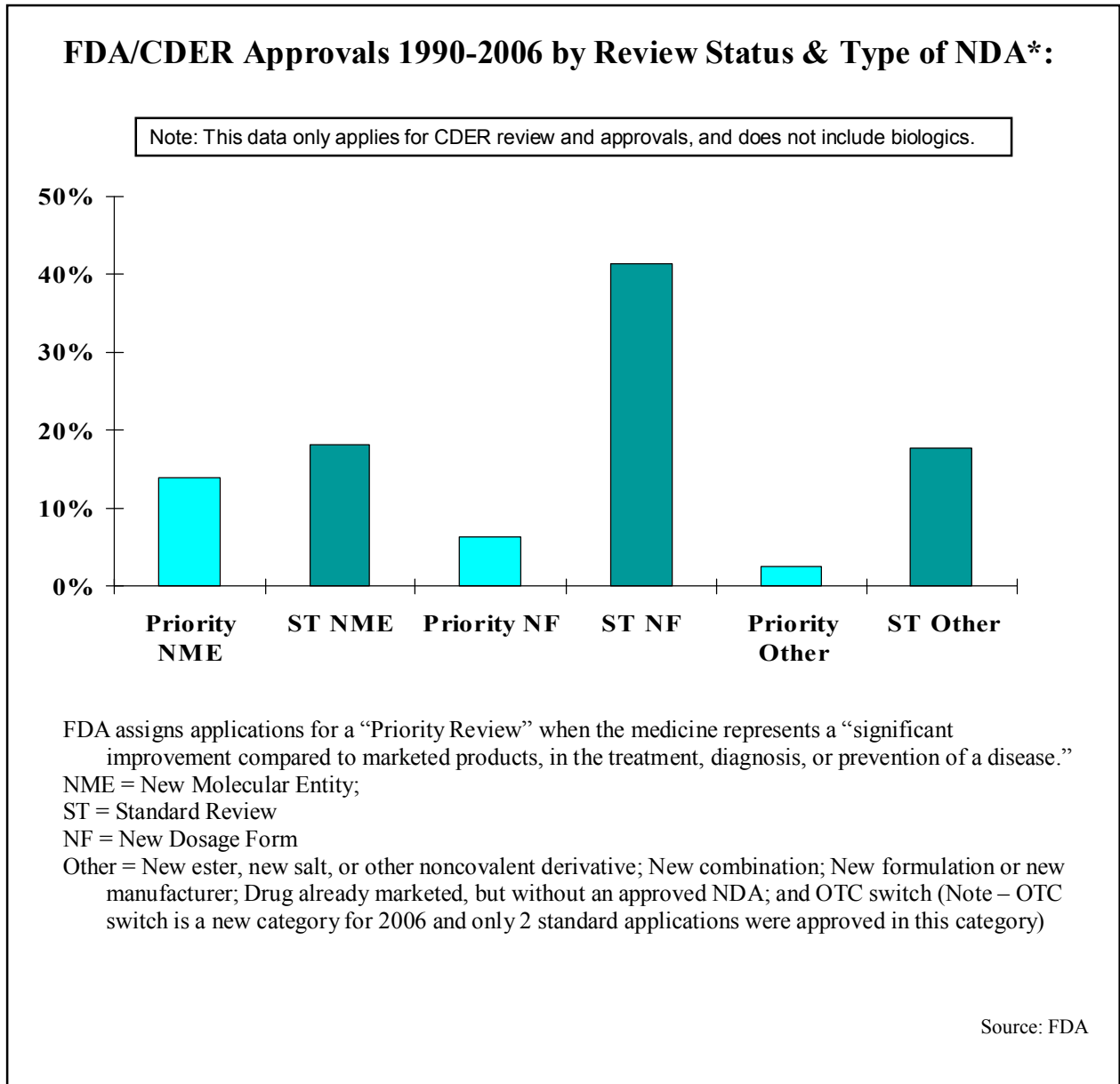


Figure 3

Percentage of FDA Approvals via Priority Review that are New Molecular Entities and New Dosage Forms of Previously Approved Compounds

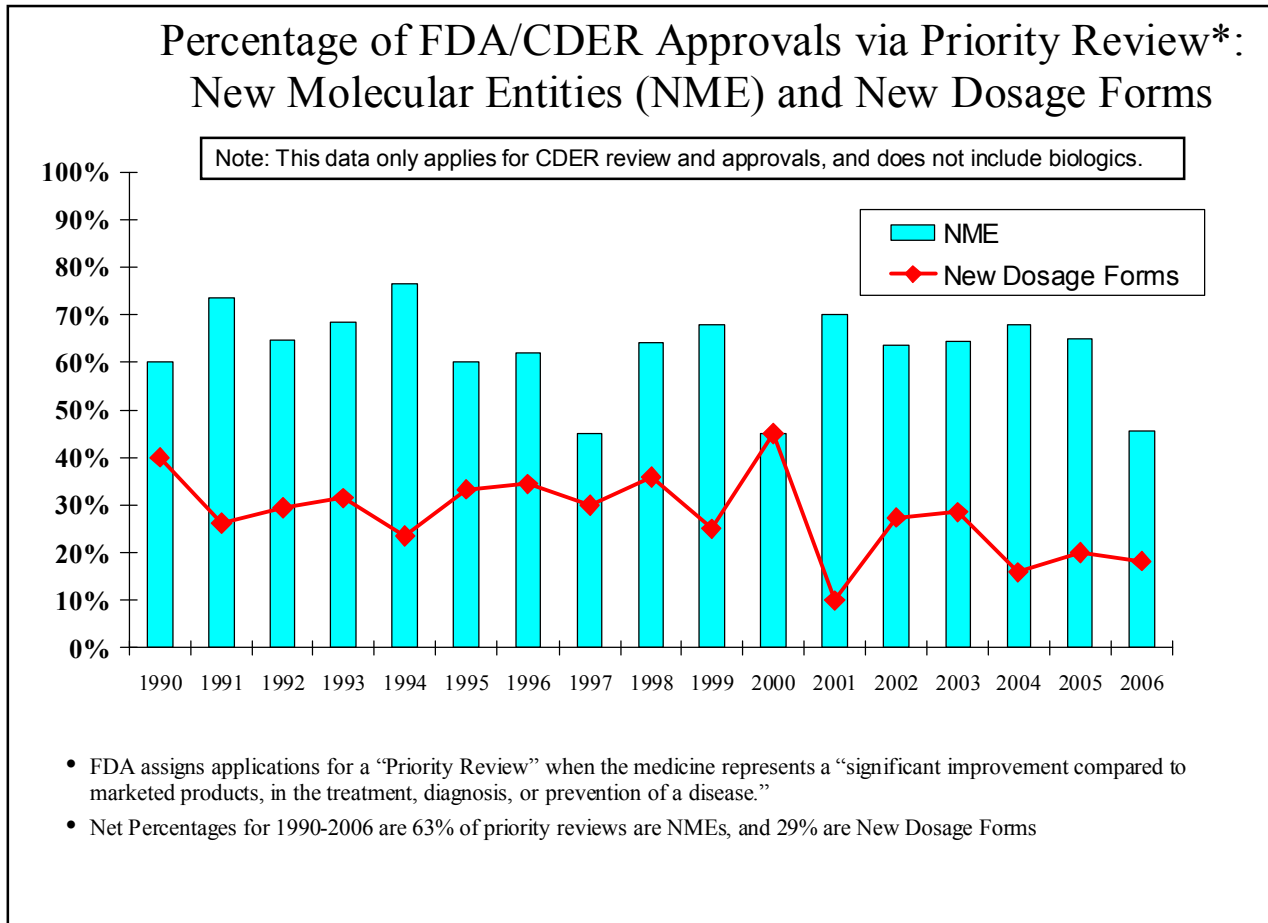


Figure 4

