98N-339D

5470 '98 AUG 19 P4:41

FDA Modernization Act of 1997 (FDAMA)

Section 406 (B):

Consult "with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups and the regulated industry..."

TS 2

Suydam/Grice, 8/98, AS

FDAMA Section 406 (b)

Objectives:

- Maximize the availability and clarity of information about the process of review of applications and submissions
- Maximize the availability and clarity of information for consumers and patients concerning new products

FDAMA Section 406 (b)

Objectives:

- Implement inspection and postmarket monitoring provisions of the Act
- Ensure access to the scientific and technical expertise necessary to meet obligations

FDAMA Section 406 (b)

Objectives:

- Establish mechanisms for meeting established time periods for the review of all applications and submissions by July 1, 1999
- Eliminate backlogs in the review of applications and submissions by January 1, 2000

Issues of Concern

- Adverse Event/Injury Reporting
- Product Safety Assurance
- Product Application Reviews

Issues of Concern

- Food Safety
- Outreach
- Scientific infrastructure and research
- Tobacco

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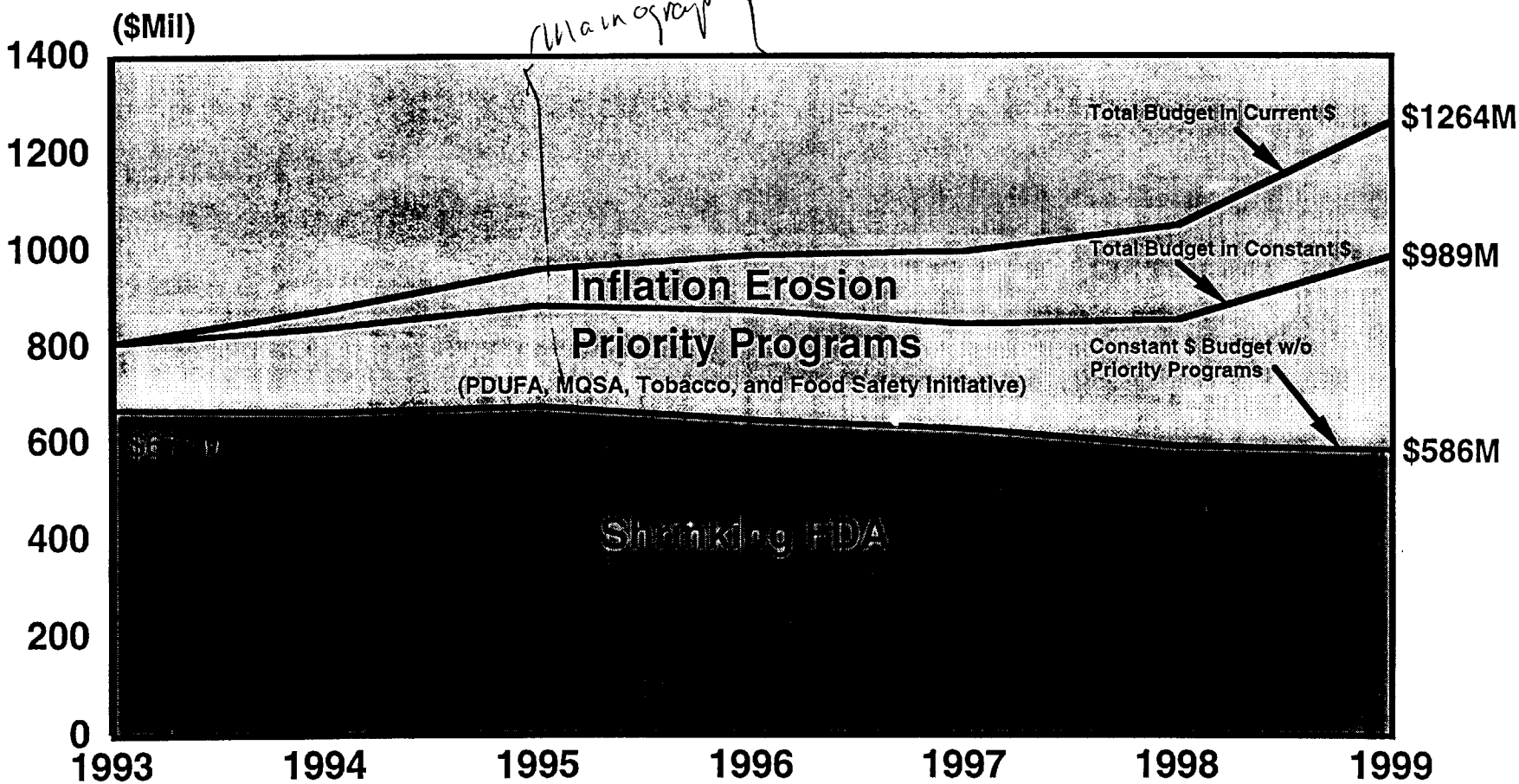
The Visible FDA



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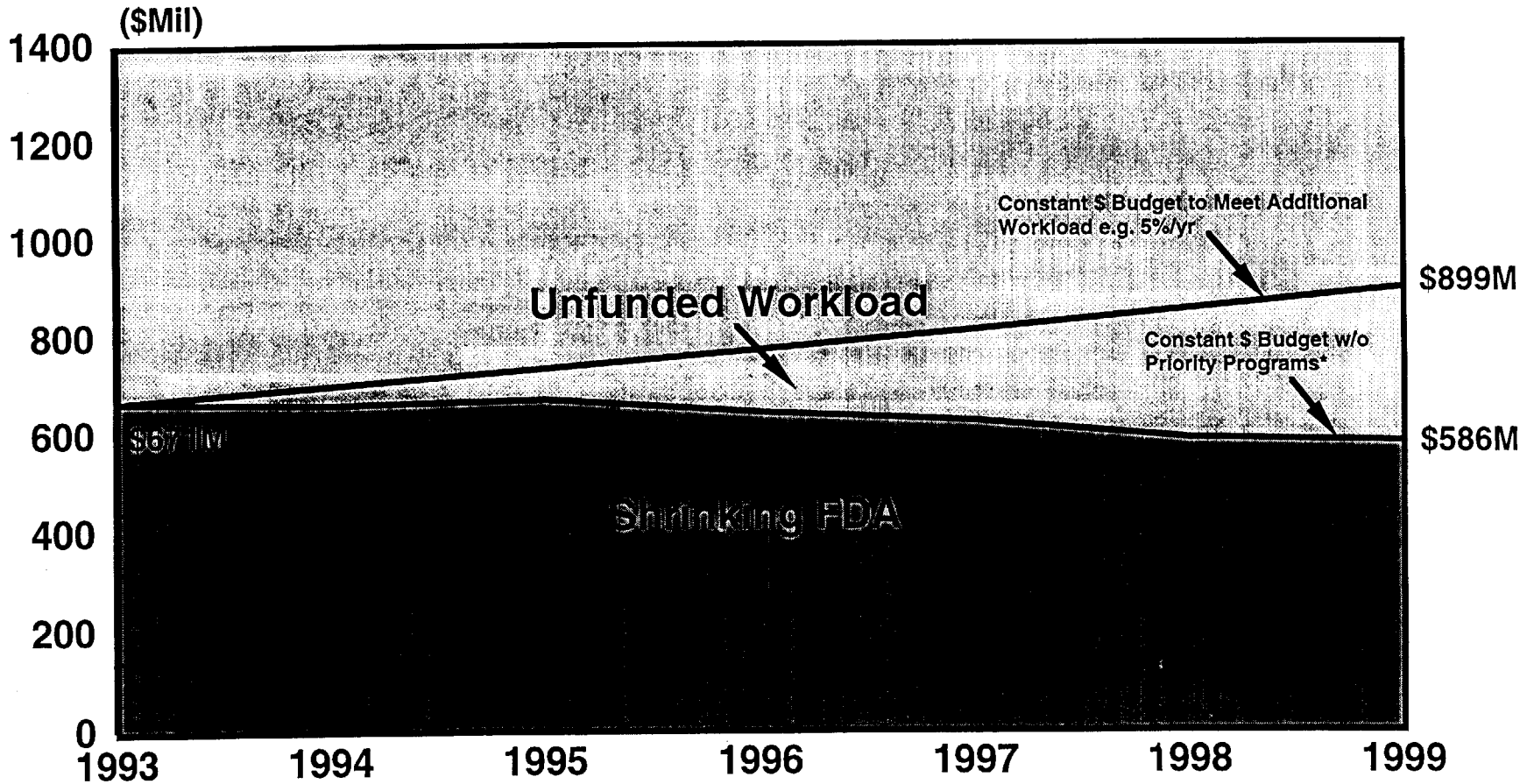
The Shrinking FDA

(Constant Dollar Effort Relative to Increasing Workload)



**Priority Programs = PDUFA, MQSA, Tobacco, and Food Safety Initiative.*

Suydam/Grice, 8/98, AS

FDA Modernization Act of 1997 (FDAMA)

Section 406 (b):

consult "with appropriate scientific and academic expe[illegible]ives of patient and consumer advocacy groups and the regulated industry..."

Docket Number 98N-0339

3 ways to comment

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