



FDA/NIH Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment

A Device Industry Perspective presented on behalf of The Advance Medical Technology Association

by

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Innovations in Glucose Monitoring

Where We Are

- Enhanced accuracy
- Speed
- Smaller sample size
- Alternate sample sites
- Trend analysis
- Ease of use
- 24-hour patient hotlines
- Special features

Where We're Going

- Continuous monitoring
- Open-loop control of insulin pumps
- Artificial pancreas
- Optimize and individualize diabetes management with actionable health information



Challenges to Innovation

- **Regulation**
- **Reimbursement**
- **Funding**



What works at FDA

- Published guidance documents
- 510(k) paradigm
- Class II for open-loop infusion pump controllers
- De novo classification
- FDAMA meetings
- Office of Combination Products
- Office of IVDs



How can FDA prepare for new technologies

- Global harmonization of premarket review program
- Develop criteria for:
 - Device down-classification
 - Claims for diabetes targeted screening
 - Review of genetic diabetes testing



Reimbursement Challenges

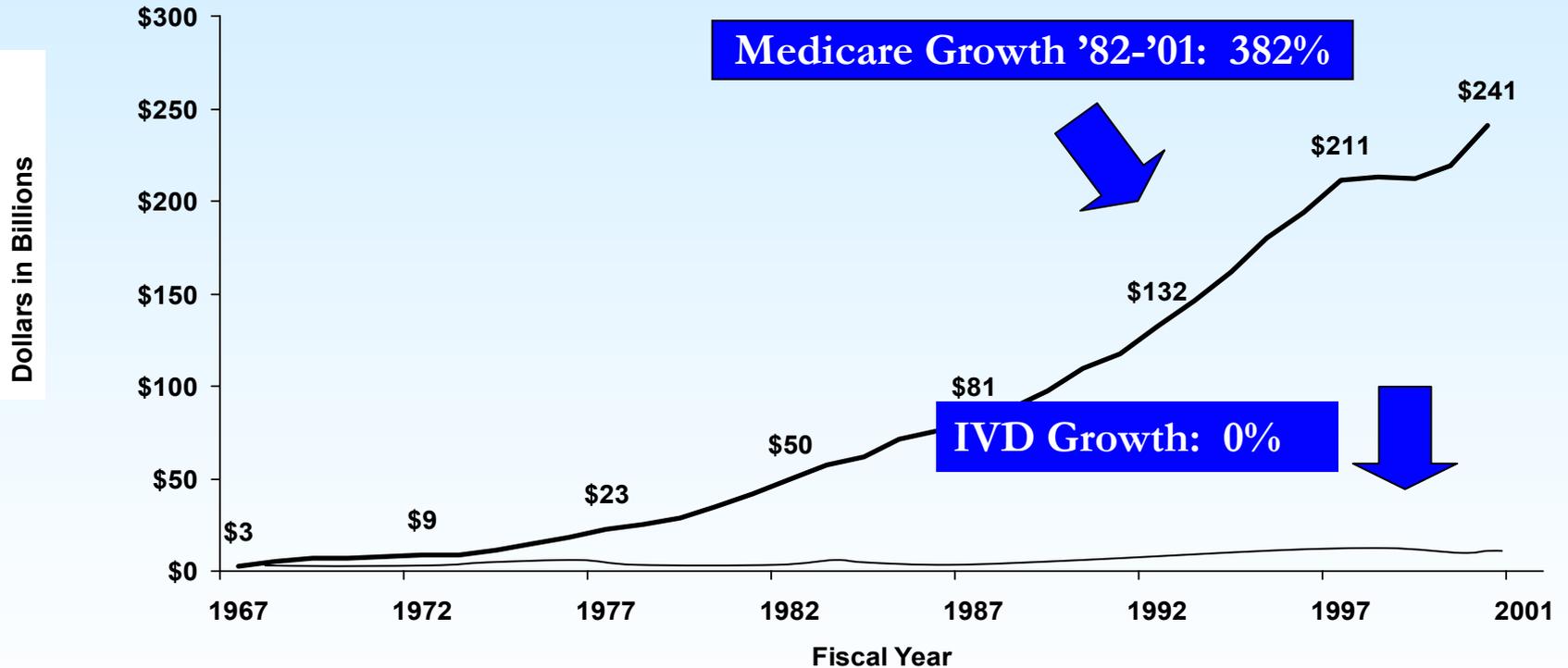
- Blood glucose monitoring equipment continually targeted for Medicare payment reductions
- Directly impacts patient access to most appropriate technology as well as new technologies and services
- High potential to affect blood glucose testing compliance
- Directly affects company investment in R&D and ability to provide value added services
- Will inhibit development of novel molecular tests and pharmacogenomic solutions



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Overall Medicare spending grew from \$3.3 billion in 1967 to nearly \$241 billion in 2001.



Note: Overall spending includes benefit dollars, administrative costs, and program integrity costs. Represents Federal spending only.

Source: CMS, Office of the Actuary.

1997

Balanced Budget Act expands glucose testing and other benefits for diabetes patients

2002

HHS Secretary Tommy Thompson says HHS will "aggressively take on preventing the onset of diseases such as diabetes" in 2002.

2002

HHS specifically notes the importance of routine blood sugar monitoring and access to glucose monitors, test strips, and other self-testing equipment.

1999

Balanced Budget Refinement Act halts glucose testing payment reduction proposed by CMS

2002

"Daily monitoring and careful control of blood sugar levels are the most important steps that people with diabetes can take."

FDA Consumer Magazine

2002

HHS says 17 million Americans have diabetes and urges citizens to guard against 'pre-diabetes.'

2002

Thompson launches first national diabetes prevention campaign called "Small Steps, Big Rewards" that stresses healthy diets and physical activity.

2003

ADA study says annual medical costs and productivity costs of diabetes increased from \$98 billion in 1997 to \$132 billion in 2002. ADA President Kaufman says, "Diabetes imposes a substantial cost burden to society."

Health Experts Advance Diabetes Monitoring & Testing

1997



2004

CMS Discourages Diabetes Monitoring & Testing

1998

CMS attempts to reduce payment for blood glucose monitoring supplies

2000

CMS restricts blood glucose monitoring for patients in nursing homes

1998

CMS proposes restrictions on diabetes monitoring supplies for non-insulin treated patients

2000

CMS initiates payment cuts for blood glucose monitoring services in nursing homes.

2001

CMS considers reducing payment level for blood glucose testing by 50 percent.

2003

Passage of MMA competitive bidding provisions limiting choice of diabetes equipment and supplies. Medicare price freeze and payment reductions for diabetes monitoring systems. IVD price freeze.



Needed Research

- Effectiveness of screening using blood glucose monitors
- Medical and economic benefits of tight glycemic control in Type 2 diabetes
- Optimizing ways to achieve the desired glycemic control



Recommendations for Fostering Innovation in Diabetes Care

- Regulations should facilitate the introduction of innovative products.
- Payment systems should place emphasis on early detection and optimization of treatment to prevent complications.
- Increase research dollars to support work that makes living with diabetes easier; look for solutions through better screening, management, and genetic, cellular and pharmacogenomic innovations.



