Effective Patent Life of Antiretroviral Drugs in the U.S 1987-2006: A Public Health Perspective

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Outline

- Background
- Study Objectives
- Data Sources
- Methods
- Results
- Conclusions
- Limitations
- Implications

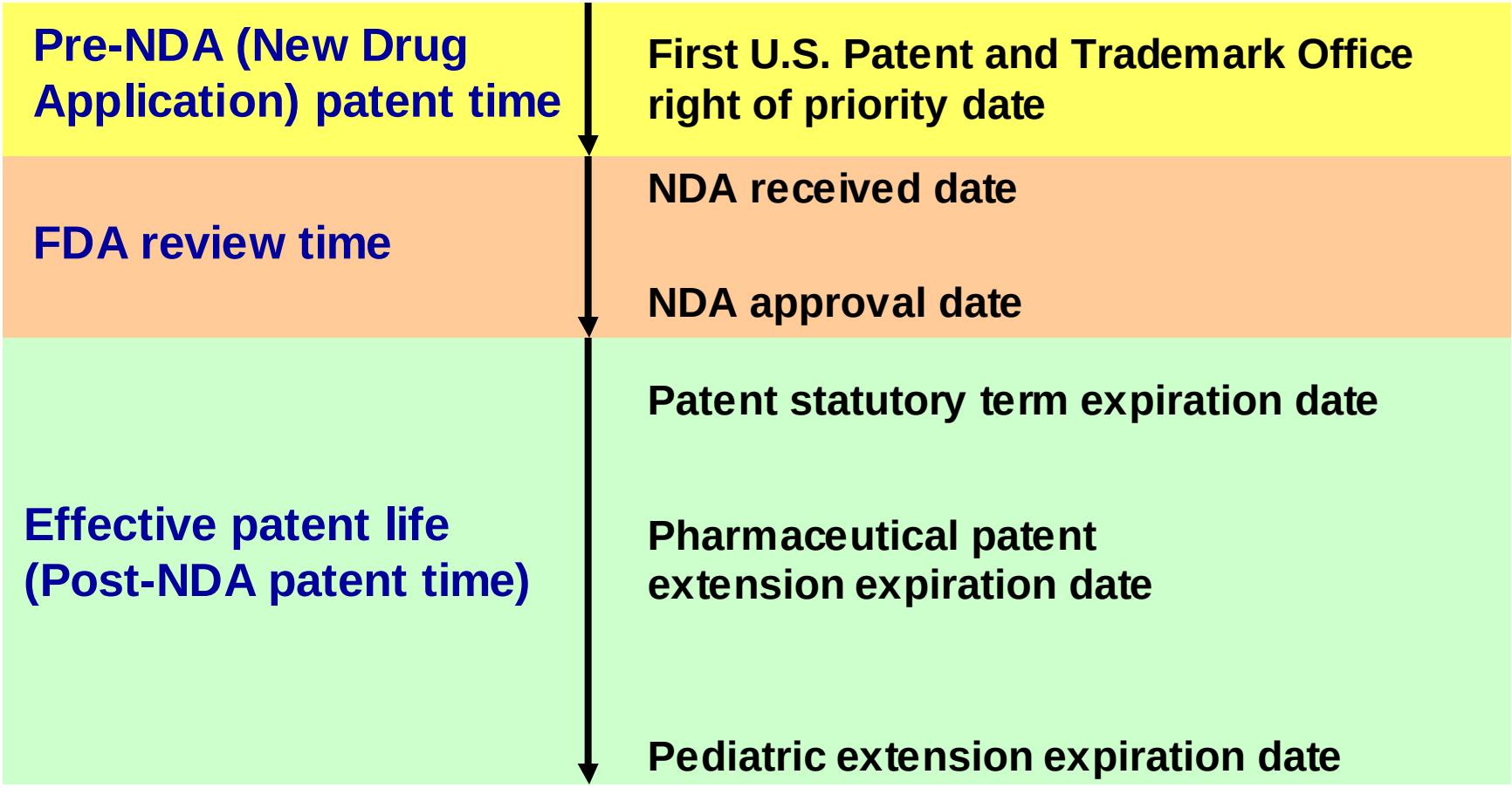
Background: Access, Prices and Patents

- Society is faced with balancing the reward from innovation for finding new drugs with adequate access to affordable drugs
- Difficult balance for antiretrovirals (ARVs) and drugs targeting life-threatening diseases
- High prices of patented ARVs reduce access
- Generic drug entry reduces prices
- Patents are the main barrier to generic entry

Study Objectives

- To examine the effective patent life periods of new molecular entities (NMEs) approved for marketing in the United States between 1987 and 2006
- To compare the effective patent life of ARVs and other therapeutic classes

Conceptual Model: Drug Patent Life



Data Sources

- FDA and U.S. Patent and Trademark Office
- NMEs approved during the period 1987-2006
- NMEs with at least one patent listed in the FDA Orange Book (OB)
  - OB lists drugs approved by the FDA and patents affecting new drugs
  - Excludes manufacturing process patents
- Drugs discontinued from the market were excluded from the analysis
- Data was updated to December 31, 2006

Methods

- First and last patents used to estimate minimum and maximum effective patent life
- A comparison between the effective patent life of ARVs and all other NMEs was performed
- Sub-analysis ARVs and all other NMEs
  - Priority review
    (FDA considered drug to be an improvement)
  - Orphan drugs
- Group comparison t-tests
- SPSS vs. 15 used for the analysis

Results

Drug Sample

532 NMEs approved in 1987-2006

- 105 without a patent listed in the OB

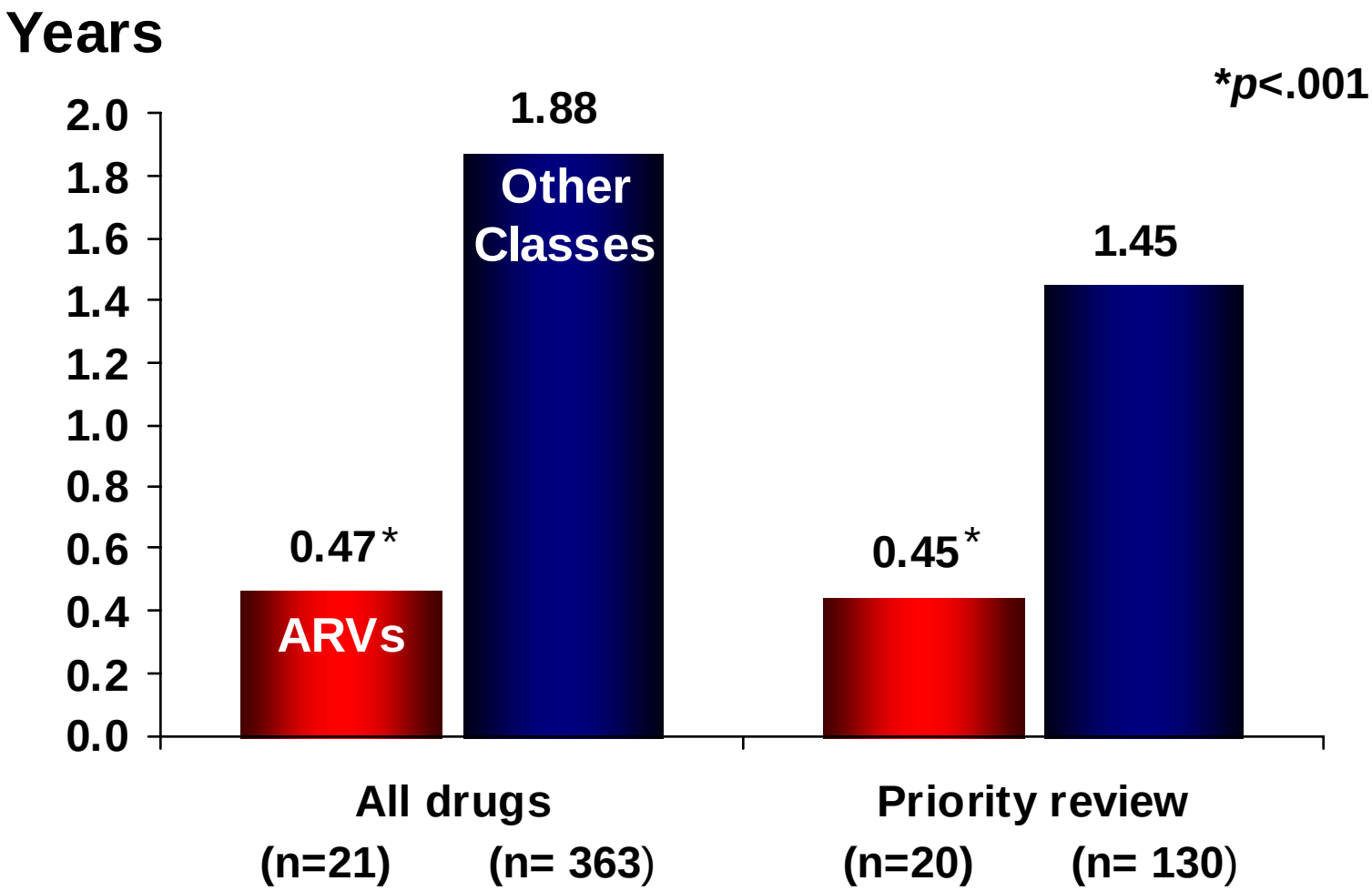
- 43 discontinued

384 included in the study

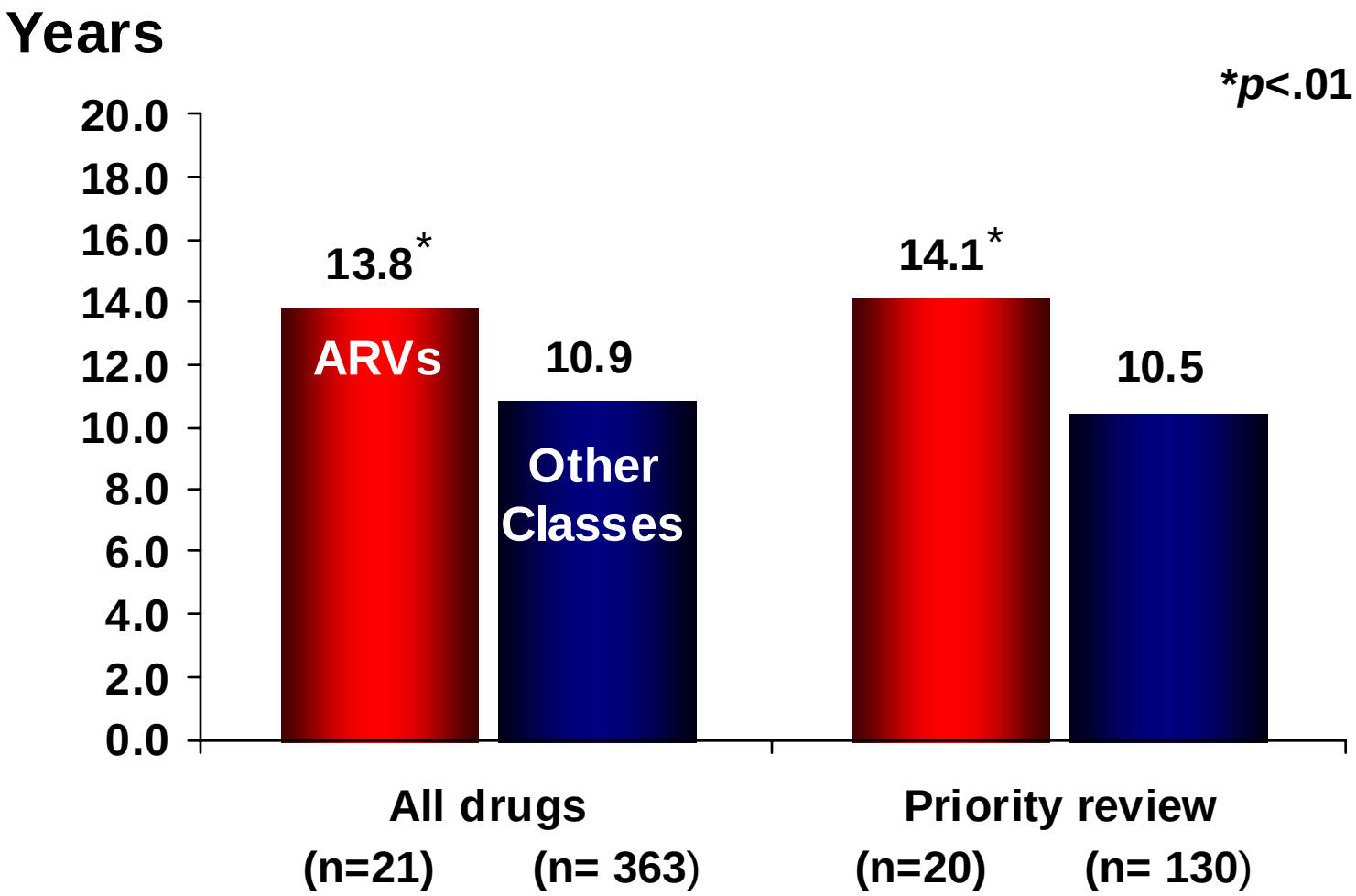
21 (5.5%) ARVs

363 (94.5%) NMEs from other classes

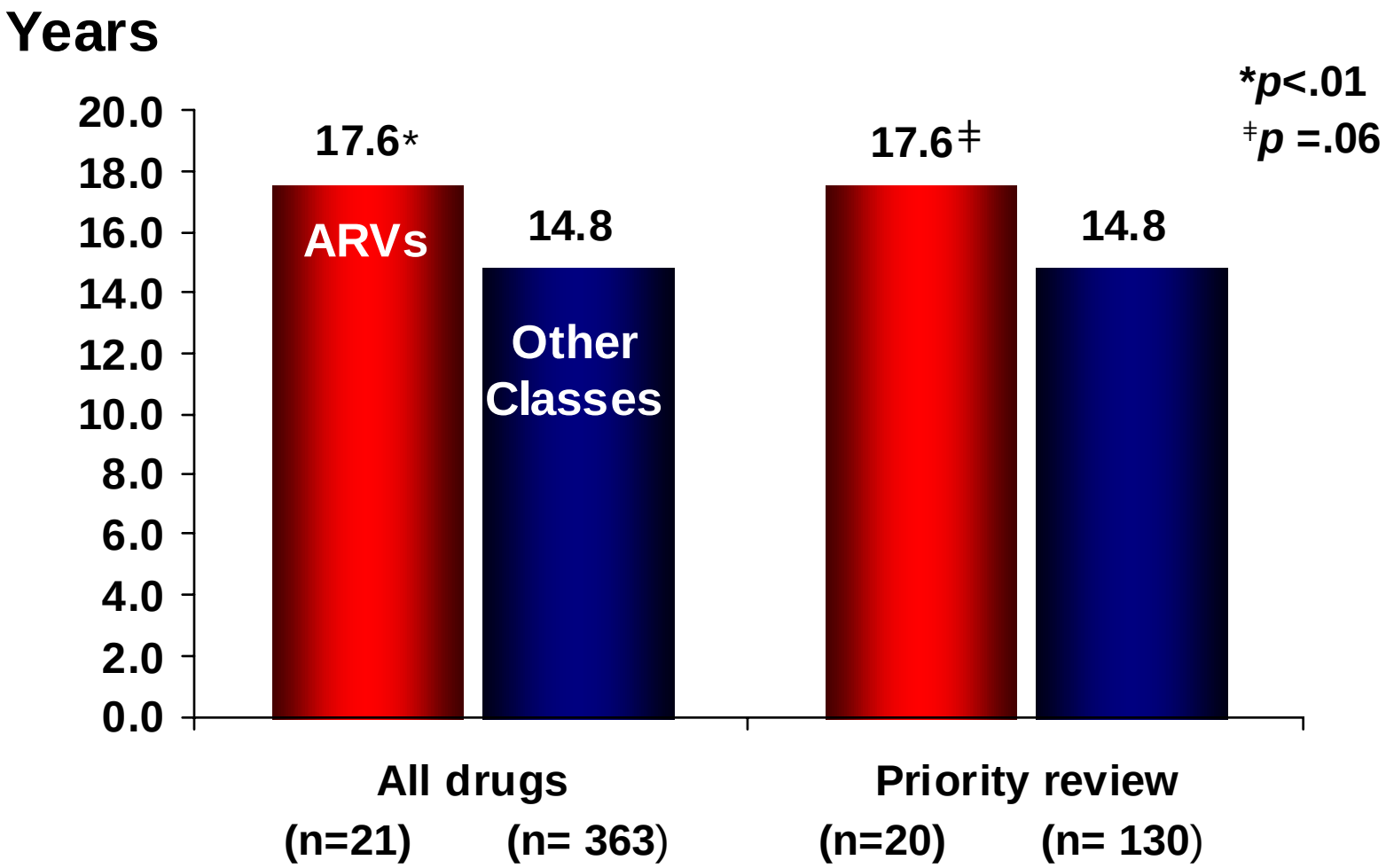
FDA Review Time. Antiretrovirals and Other Therapeutic Classes. 1987-2006



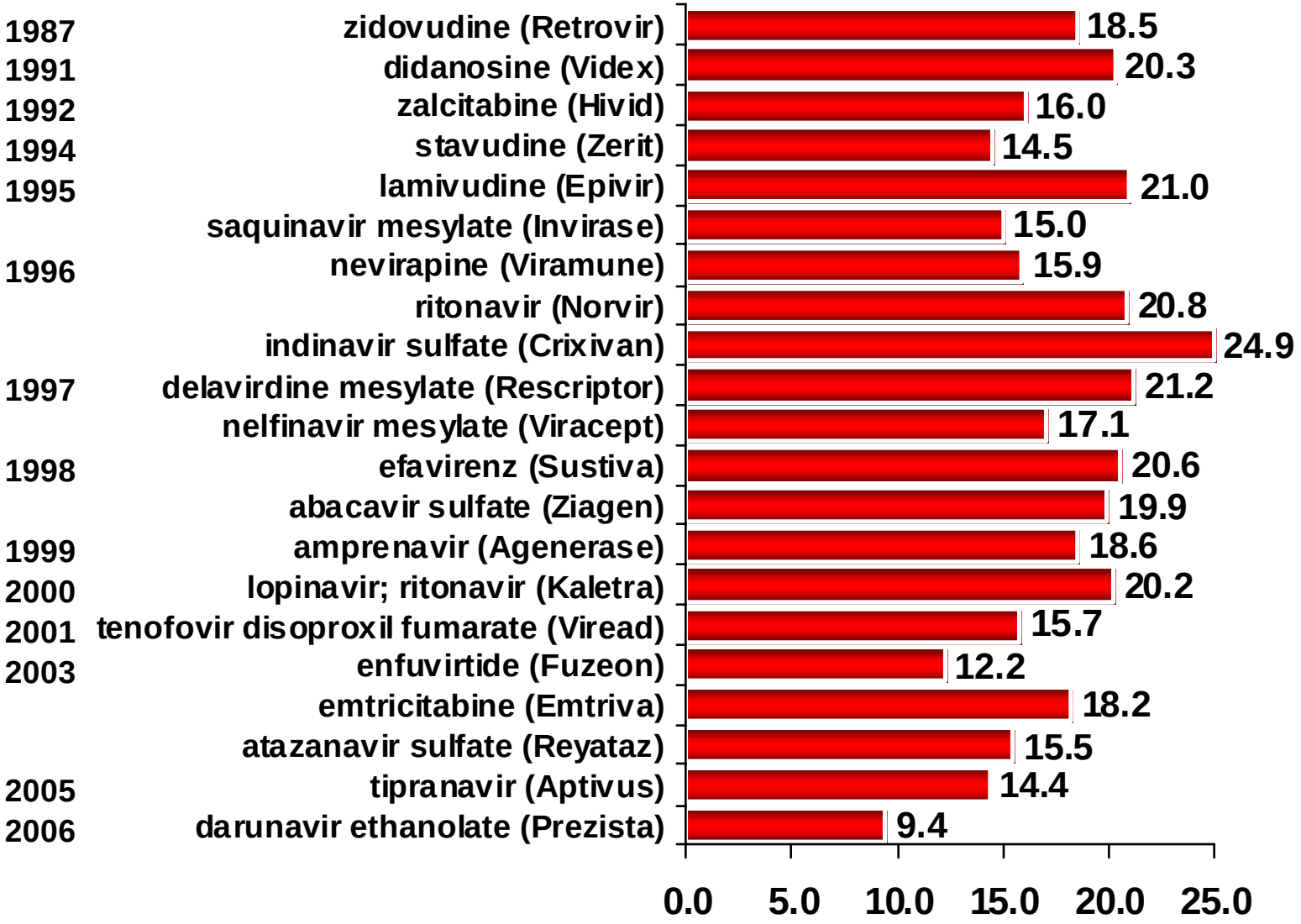
FDA NDA Approval to First Patent Expiration Time. Antiretrovirals and Other Therapeutic Classes. 1987-2006



FDA NDA Approval to Last Patent Expiration Time. Antiretrovirals and Other Therapeutic Classes. 1987-2006



Time from FDA NDA Approval to Last Patent Expiration. ARVs, 1987-2006



Conclusions, Limitations and Implications

Conclusions

- Statistically significant difference in effective patent life of ARVs vs. other classes
- ARVs had an average of 2.9 years more effective first patent life than other classes
- ARVs had an average of 2.8 years more effective last patent life than other classes

Conclusions

- Shorter ARV FDA review time explains 50% of the difference in effective patent life
- Effective patent life for the last patent of 7 ARVs (33.3%) exceeded 20 years

Limitations of the Study

- **Subject Selection**
  - **Includes first product number of the first NDA and excludes successive NDAs (line extensions)**
- **Patent Selection**
  - **Includes first and last patent listed in the OB**
  - **Excludes other patents listed in the OB and patents not listed**
- **Intellectual property**
  - **Excludes intellectual property rights other than patents (i.e. exclusivity)**

A Public Health Perspective

- **Shortening ARV development and the FDA drug review process increased ARV effective patent life**
  - **Faster entry to new drugs**
  - **Potential for improved access for HIV patients**
- **Implications for other therapeutic categories**
  - **ARVs higher risk benefit ratio than other therapeutic classes**
  - **Pandemic disease**
  - **Perspectives: Patients, FDA, Health plans, Industry**

A Public Health Perspective (&2)

- ARV may generate higher rewards for pharmaceutical companies
  - Less development opportunity costs
  - Longer effective patent life without generic competition
- Need for balancing intellectual drug property rights and access to ARVs
  - Balance at the therapeutic category level

An International Public Health Perspective

- **The U.S. pharmaceutical patent and FDA exclusivity system exceeds TRIPS**
  - **Patent extensions and pediatric exclusivity**
- **Bilateral agreements may extend pharmaceutical intellectual property protection in developing countries**
  - **Effects on prices and access**

TRIPS: Trade-Related Aspects of Intellectual Property Rights (World Trade Organization)

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