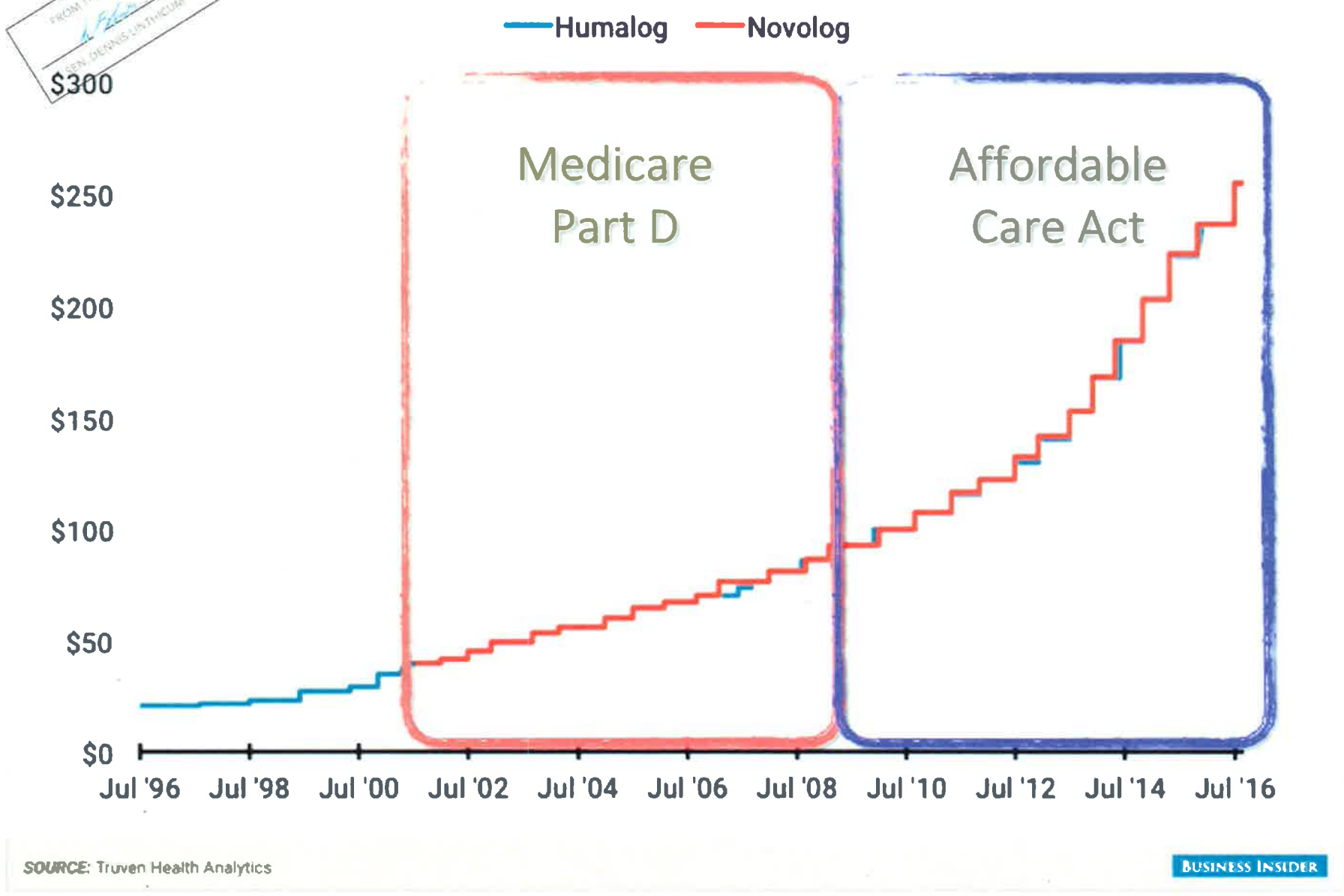
Rising Insulin Prices

400SB

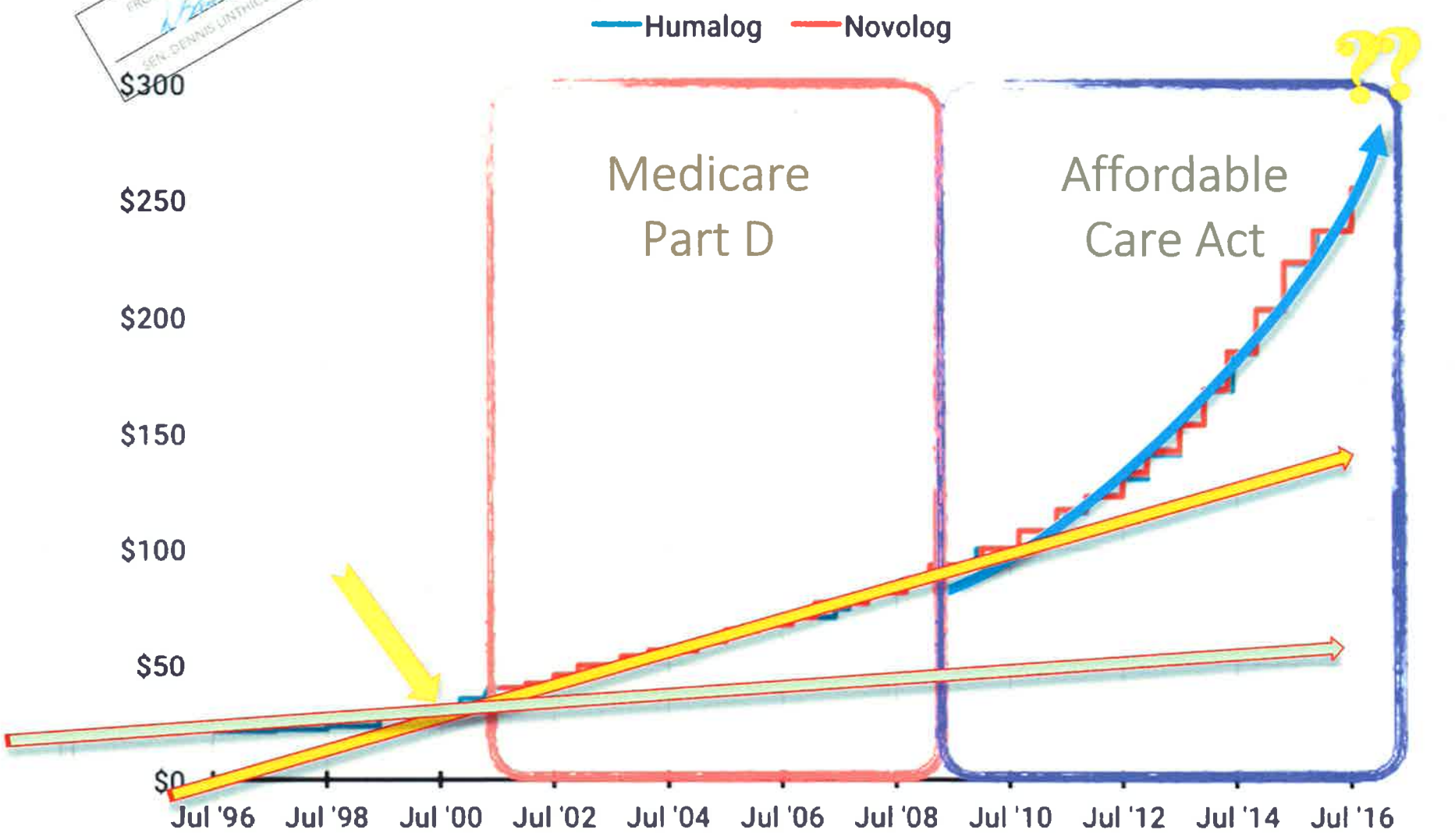
RISING INSULIN PRICES



SOURCE: Truven Health Analytics

BUSINESS INSIDER

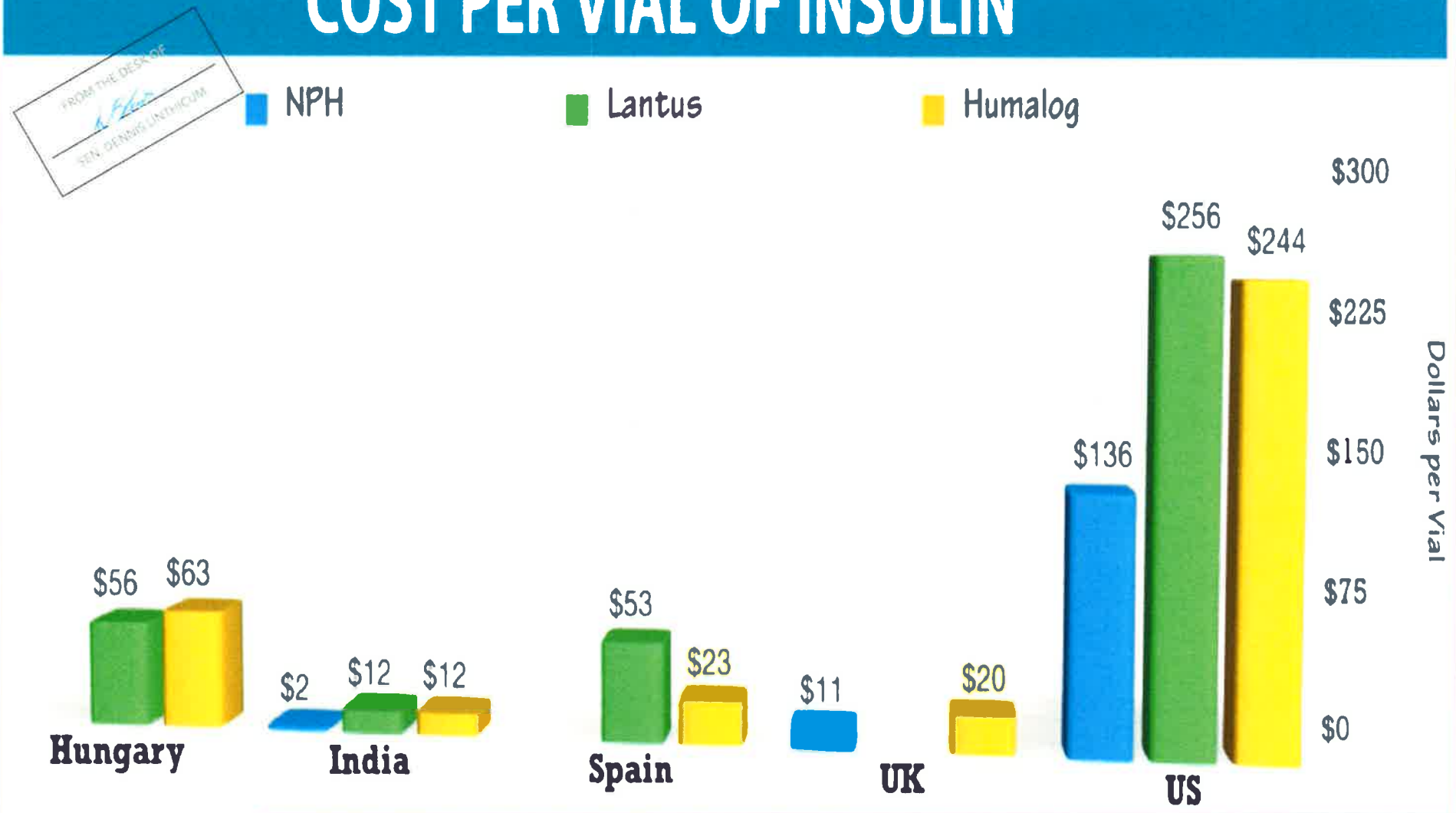
RISING INSULIN PRICES



SOURCE: Truven Health Analytics

BUSINESS INSIDER

COST PER VIAL OF INSULIN



Medscape

Comparing Insulin Prices Around the World (Feb., 2016)

Year	2000	2018
Price/Vial	$30	$330
Months	12	12
Patients	1,000,000	1,600,000
Sales	$360 Million	$6.33 Billion

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 203 PRESCRIPTION DRUG MARKETING

Subpart B--Reimportation

Sec. 203.10 Restrictions on reimportation.
No prescription drug or drug **composed wholly or partly of insulin** that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug **or insulin-containing drug** if it determines that such reimportation is required for emergency medical care.

Sec. 203.11 Applications for reimportation to provide emergency medical care.
(a) Applications for reimportation for emergency medical care shall be submitted to the director of the FDA District Office in the district where reimportation is sought (addresses found in part 5, subpart M of this chapter).
(b) Applications for reimportation to provide emergency medical care shall be reviewed and approved or disapproved by each district office.
[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 17292, Apr. 2, 2004]

Sec. 203.12 An appeal from an adverse decision by the district office.
An appeal from an adverse decision by the district office **involving insulin-containing** drugs or human prescription drugs or biological products regulated by the Center for Drug Evaluation and Research may be made to the Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. An appeal from an adverse decision by the district office involving human prescription biological products regulated by the Center for Biologics Evaluation and Research may be made to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002.
[80 FR 18090, Apr. 3, 2015]

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.
Source: 64 FR 67756, Dec. 3, 1999, unless otherwise noted.