NEWS IN BRIEF

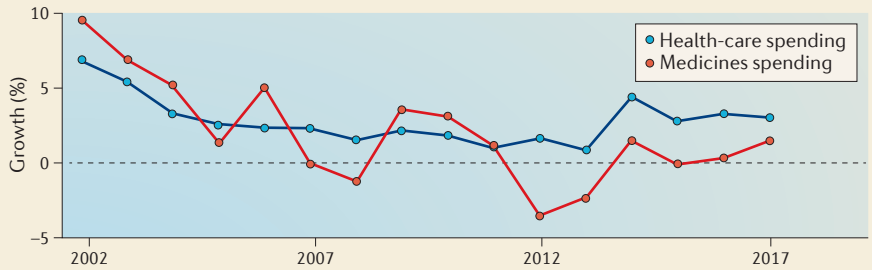
Drug spending down

The United States spent 3.5% less per capita on medicines in 2012 than in 2011.

The lowdown: The United States spent US$325.8 billion on branded and generic medicines in 2012, down from $329.2 billion in 2011, wrote IMS Health analysts in their report *Declining Medicine Use and Costs: For Better or Worse?* (go.nature.com/w4BUNW). Spending on branded products, in particular, fell by $11.4 billion to $230.2 billion. The IMS authors ascribe the overall fall (a nominal fall of 1%, or a per capita adjusted fall of 3.5%) to declining use of branded drugs, greater availability of lower-cost generics and lower levels of price increases. They forecast that overall medicine spending will continue to fall in 2013 before picking up again in 2014 (see the figure). Health-care spending is due to continue to grow at a faster rate than medicine spending, the authors report.

The top therapeutic area last year based on spending was oncology ($25.9 billion), in which an increase in spending was driven primarily by targeted agents that were launched in 2011. Mental health drug spending was down almost 20% (to $23.5 billion), whereas respiratory drugs ($22.1 billion), antidiabetics ($22 billion) and pain ($18.2 billion) were up from 2011 levels. The areas that saw the biggest increases in spending were antivirals, multiple sclerosis, attention deficit hyperactivity disorder and autoimmune diseases.

New drugs, defined as products that have been on the market for fewer than 24 months, also fared well. Spending on new drugs was $10.8 billion in 2013, up from $10.3 billion in 2011. This increase was driven by a surge in the success of specialty medicines, which accounted for two-thirds of the new drug spending last year. The top five new specialty drugs were Vertex's telaprevir for hepatitis C virus, Sanofi and Regeneron's aflibercept for wet age-related macular degeneration, Amgen's denosumab for bone metastases, Novartis's fingolimod for multiple sclerosis and Bristol-Myers Squibb's ipilimumab for metastatic melanoma.



Source: IMS Health.

Clinical trial transparency plans hit a snag

The EMA's plans to release anonymized patient-level data from clinical trials to investigators have hit a snag with temporary injunctions against data disclosure from the General Court of the European Union.

The lowdown: The European Medicines Agency (EMA) has been releasing clinical trial data to investigators on a per-request basis since 2010, and took steps last year towards adopting a more proactive, consistent data release programme (see *Nature Rev. Drug Discov.* **11**, 891–892; 2012). Under one plan, a group of independent experts would review requests for patient-level data before releasing information to academic or industry investigators. But two pharmaceutical companies — AbbVie and InterMune — have sued to prevent the release of "confidential and commercially sensitive" information following freedom of information requests to the EMA for data. The General Court of the European Union granted injunctions in April preventing the release of the data. The injunctions are temporary until the court reaches a full decision on the cases, and the EMA says it is considering appealing. Many requests for data have come from industry, rather than academic groups, the EMA has said.

The transparency setback came as the EMA released final advice from a clinical trial advisory group on "good analysis practice" (go.nature.com/DdqOlL). This and four other reports will help inform the EMA as it drafts its policy on access to clinical trial data. A draft policy is due by the end of June, and will then be open for comments for a few months. The final policy is due by the end of November, to be implemented by 1 January 2014.

GlaxoSmithKline (GSK), meanwhile, has moved ahead with its own plans to make clinical trial data accessible to the research community. Investigators can ask for anonymized patient-level data from a set of studies via an online portal (clinicalstudydata.gsk.com), and requests (which must include a scientific protocol) will be assessed by an independent panel of experts before access is granted. GSK plans to eventually make data available from back to December 2000. "We are the first organization to develop a system for sharing detailed clinical data in this way. Now we want to see this initiative transition to a broader independent model that brings together data from multiple organizations," said GSK's President of Pharmaceuticals research and development (R&D) Patrick Vallance.

Biotech "not completely out of the woods"

Biotech's revenue and R&D spending growth was slower in 2012 than in 2011, shows an Ernst & Young report.

The lowdown: Ernst & Young analysts reviewed the data from 598 public biotech companies in their 27th annual *Beyond Borders* report on the health of the biotechnology sector, and came up with mixed results (go.nature.com/5igfsV). Although research and development (R&D) expenses — a bellwethers of the state of the industry — were up 5% (to $25.3 billion), this growth rate was down from the 9% increase achieved in 2011. "The distribution of these expenditures was more worrying than the totals. Across these major markets, R&D spending by commercial leaders remained strong, while smaller, pre-commercial entities substantially reduced the pace of growth," wrote Ernst & Young's Glen Giovannetti and Gautum Jaggi. In the United States, for example, commercial leaders increased their R&D spending by 18%, whereas other companies decreased spending by 5%.

Revenue similarly was up 8% in 2012 (to $89.8 billion), but this growth was slower than the 10% achieved in 2011. On the financing side, the vast majority of small venture-backed firms still have access to only pre-financial crisis levels of capital, a phenomenon the authors dubbed "the new normal" in 2012.

"While biotech's financial metrics continue to be healthier than they were in the immediate aftermath of the crisis, the sector is not completely out of the woods," they write.