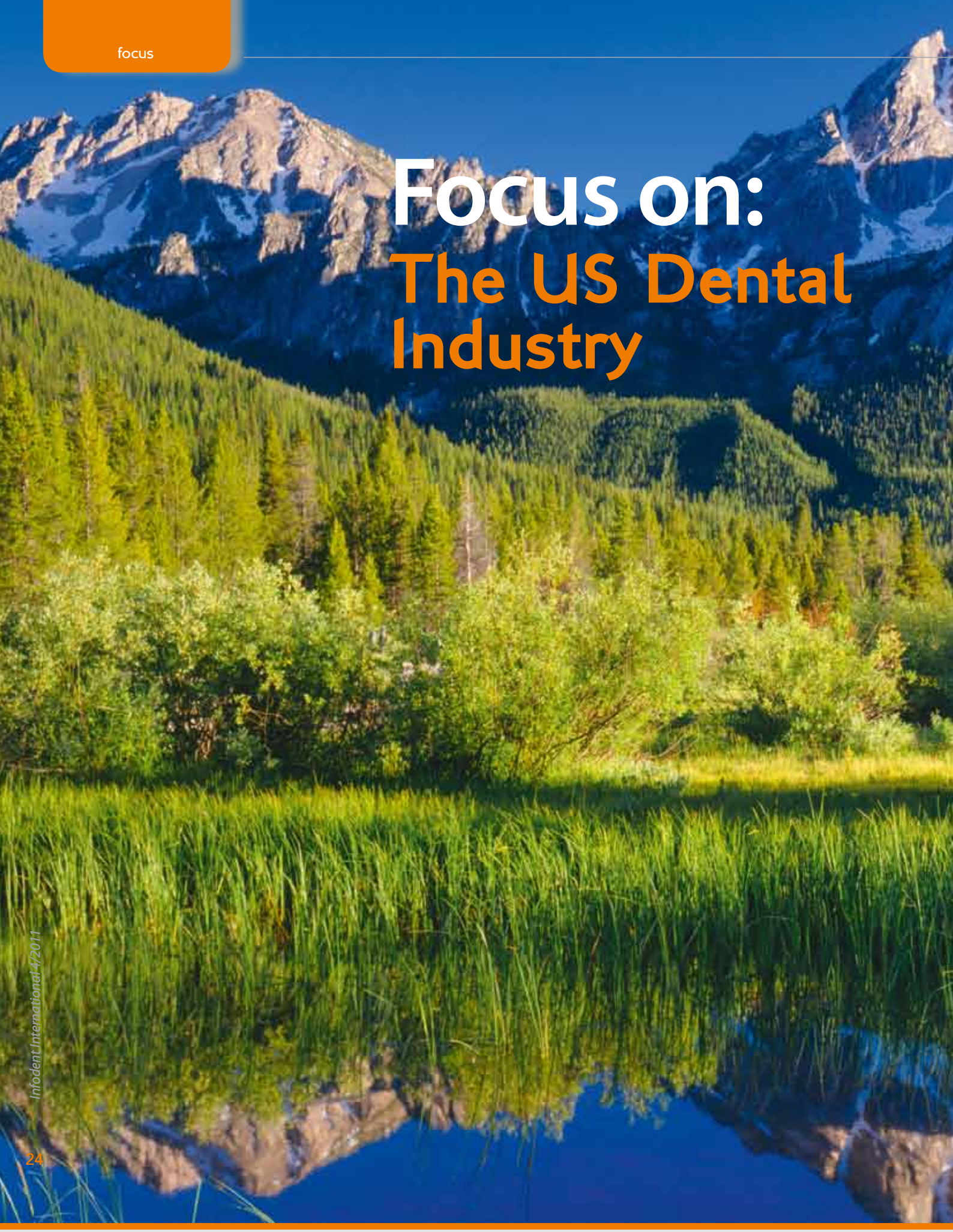
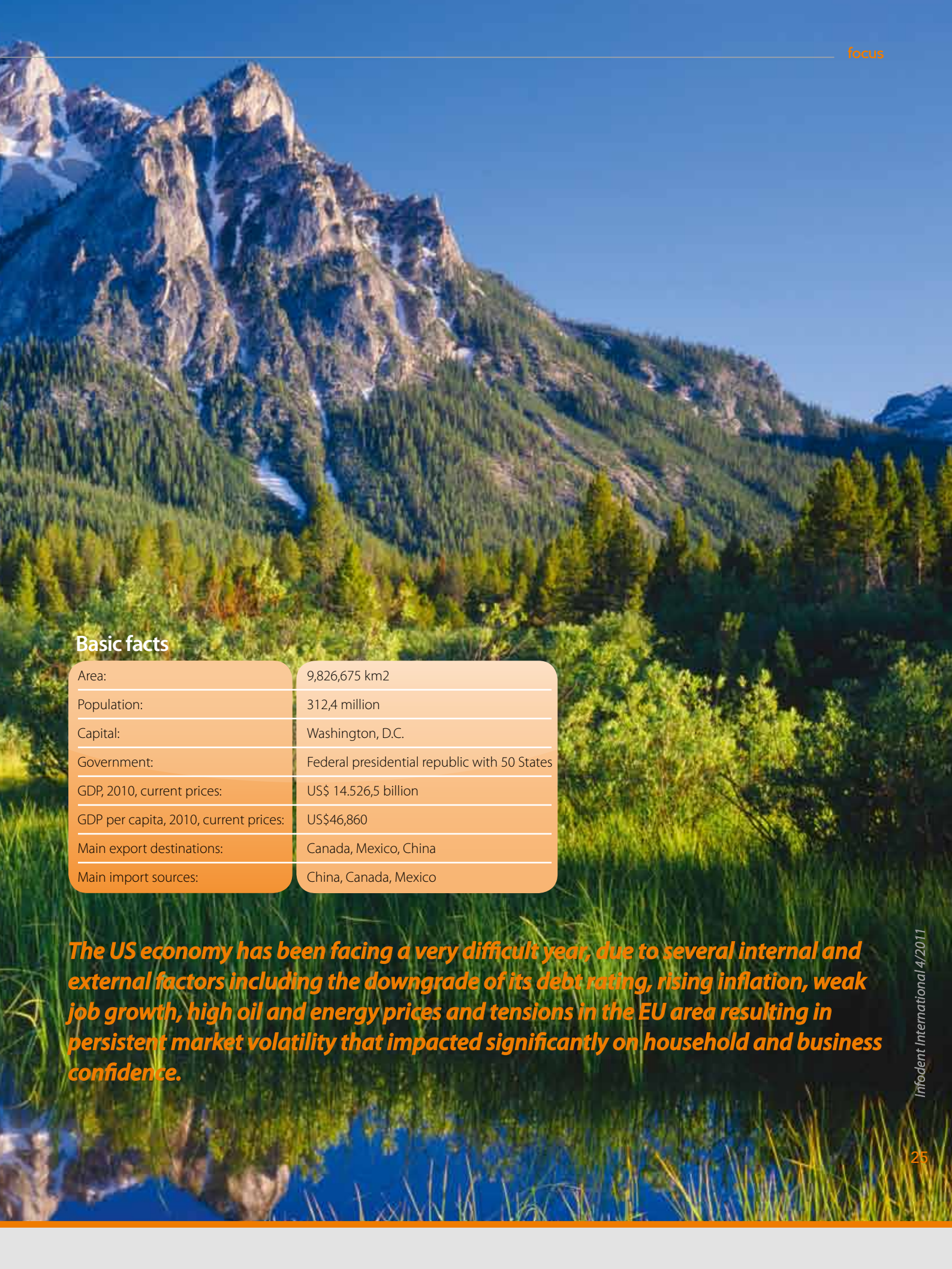


Focus on:
The US Dental Industry

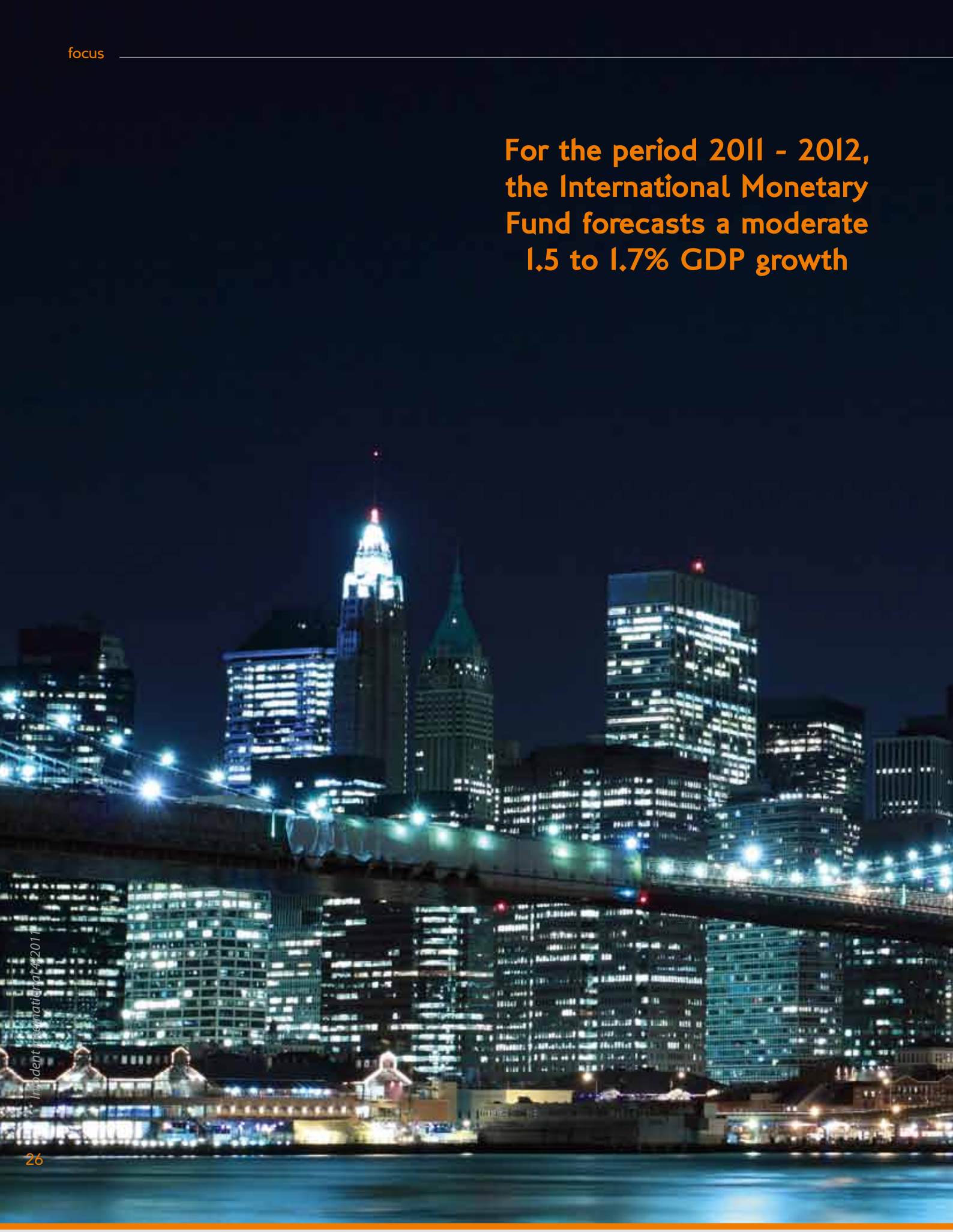


Basic facts

Area:	9,826,675 km2
Population:	312,4 million
Capital:	Washington, D.C.
Government:	Federal presidential republic with 50 States
GDP, 2010, current prices:	US$ 14.526,5 billion
GDP per capita, 2010, current prices:	US$46,860
Main export destinations:	Canada, Mexico, China
Main import sources:	China, Canada, Mexico

The US economy has been facing a very difficult year, due to several internal and external factors including the downgrade of its debt rating, rising inflation, weak job growth, high oil and energy prices and tensions in the EU area resulting in persistent market volatility that impacted significantly on household and business confidence.

For the period 2011 - 2012, the International Monetary Fund forecasts a moderate 1.5 to 1.7% GDP growth



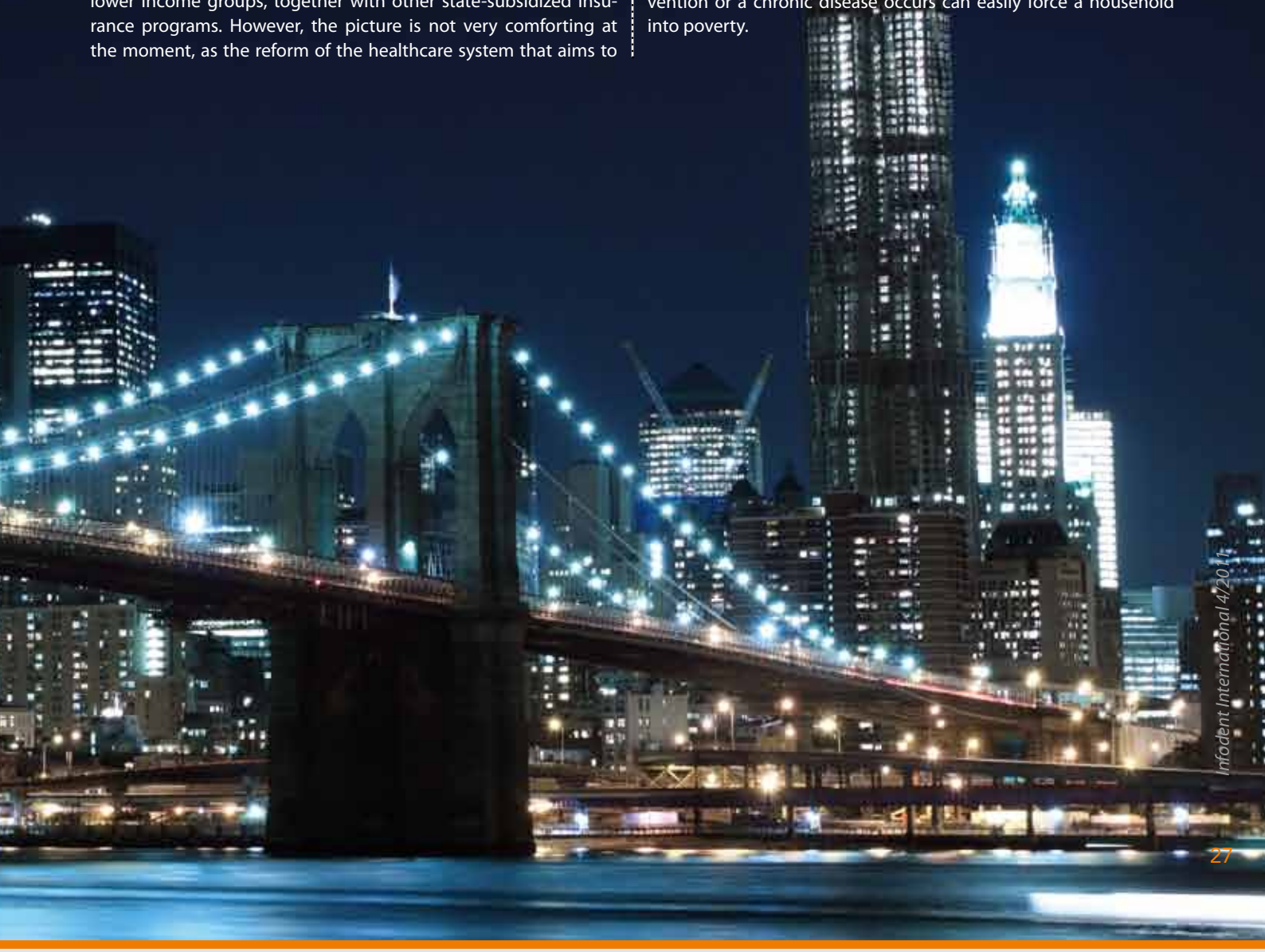
The US Department of Commerce estimated 1.3% annual increase for real GDP in the second quarter of 2011, after weak 0.4% growth in the previous quarter, a slight increase that is mainly due to a deceleration of imports and rising federal government expenditure that counterbalanced the lower consumer spending. Exports of goods slowed in 2011 but were partly compensated by a pickup in exports of services. However, both State and local government spending decreased and personal income also slowed down in consequence of higher social contributions.

For the period 2011 - 2012, the International Monetary Fund forecasts a moderate 1.5 to 1.7% GDP growth, which is likely to remain modest through 2012 and 2013 in comparison to the pre-crisis era.

Issues in Medical Coverage

The main indicator of the ability of US citizens to afford adequate healthcare services is the profile of health insurance coverage. About half Americans under 65 obtain health coverage as an employer benefit. The federal social assistance programs, Medicare and Medicaid, are responsible for coverage of elderly, children and lower income groups, together with other state-subsidized insurance programs. However, the picture is not very comforting at the moment, as the reform of the healthcare system that aims to expand coverage to the majority of the American population has to deal with the necessity of tighter fiscal policies and budget cuts, while the number of uninsured increases due to the struggling economy and the high unemployment rate. In the last decade, the decline in employer-sponsored health coverage caused a growing number of uninsured; currently, the percentage of people covered by this type of health insurance is about 55.8%.

According to the "National Health Interview Survey, January - March 2011", approximately 46.5 million people, or 15% of US population, lack health insurance, and further 25 million are underinsured because their insurance does not provide sufficient financial protection. More than three-quarters of the uninsured come from working families, and four in ten are individuals and families with incomes below the federal poverty level of $22,050 for a family of four. Most of them are adults, who have limited eligibility for Medicaid compared to children, but cannot afford private insurance or benefit from coverage provided by an employer. Lack of coverage for medical bills exacerbates the financial burdens of the unemployed and leads lower income people to delay even urgent treatments to satisfy other essential needs, and in worse cases, the impact of medical expenses especially when an emergency intervention or a chronic disease occurs can easily force a household into poverty.



On general terms, there are important economic, employment and health disparities across states and communities. Patients living in poor inner-city and rural areas are the less favoured, and many in the lower income groups seek treatment in community health centers (CHCs), free clinics and public or nonprofit hospitals that treat low-income patients. Some of them are located in such underserved, depressed rural and inner-city communities, and they also take care of providing patient outreach, case management, health education and referrals. However, the current economic conditions have caused a rising demand while funds and other forms of institutional support are often declining.

On the other hand, according to the Association "AmeriCares", the safety net of Medicaid and the Children's Health Insurance Program (CHIP) has played an important role in preventing a larger increase in the uninsured and, in particular, in safeguarding children from fully paying the consequences of the economic turmoil. June 2010 Medicaid enrolment nationwide exceeded 50 million.

Oral healthcare delivery

As reported by the National Association of Dental Plans, virtually all Americans with a dental policy obtain it through an employer, union or public program. About 85% of employees pay all or part of the cost of their dental coverage, while only 1% of dental policies are purchased by individuals.

Employers usually provide three types of policies: for employee, for employee with a dependent (spouse or child), or for employee and family. With the exception of the federal Children's Health Insurance Program (CHIP) program, child-only policies are rarely offered in the private market.

Dental policies are a separate product, distinct from medical coverage. About 98% of Americans with private dental coverage have it separated from their medical policy, and also provided by a different carrier, due to the peculiar characteristics of dentistry and dental services as compared to general health care delivery.

Access to oral health services highly depends from an individual's ability to get and keep dental insurance. In the report "Americas dental insurance crisis" CBS News gives an impressive figure stating that 100 million people, that means one-third of the country, is without dental insurance. Limited dental coverage is provided to children up to 21 years of age through the Children's Health Insurance Program (CHIP) and Medicaid, the latter alone covering about 28 million children, but only nine States provide Medicaid dental coverage for adults and in many cases, the report claims, dentists don't accept it.

More specifically, all individuals under 21 are covered to an extent that varies according to the different state policies: for instance, Alaska, Arizona, Hawaii, Maine, Michigan, Nevada, New Hampshire, Oklahoma, South Caroline, Tennessee, Virginia, Wisconsin, and Wyoming provide care primarily in emergency situations, or cover basic critical care. The other states grant more extended dental services but each state poses limits on the number of visits in a year or co-payments. However, preventative care is generally available with dental exams and cleanings.

The Patient Protection and Affordable Care Act (ACA), signed in 2010 by President Obama, is expected to improve access to oral health by expanding the Medicaid program and providing premium subsidies to make private insurance more affordable for households below specific thresholds in federal poverty levels. With the upcoming expansion of Medicaid eligibility, the number of people covered by this public program is expected to rise by almost 16 million by 2019. Over 5 million children are expected to get first-time access to dental coverage as a result of ACA, with most of them being added to public programs.

Overview of the Dental Market

According to the American Dental Association, there are nine recognized dental specialties in the U.S.: orthodontics, oral and maxillofacial surgery, pediatric dentistry, periodontics, prosthodontics, endodontics, dental public health, oral pathology, and oral and maxillofacial radiology.

Dental policies are a separate product, distinct from medical coverage. About 98% of Americans with private dental coverage have it separated from their medical policy, and also provided by a different carrier, due to the peculiar characteristics of dentistry and dental services as compared to general health care delivery.

Approximately 85% of dental care is provided by general dentists in an office setting, usually by a solo practitioner. About 81% of dentists are general practitioners. As reported in ADA surveys for 2008, among private practitioners, solo dentists were 59.8%, while 22.0% worked with one other dentist, and 18.2% with two or more dentists.

Number of dentists

Professionally active dentists	186,084
of which private practitioners	170,694 (this figure is included in the former)
Orthodontists	7,700
Oral and maxillofacial surgeons	6,700
Prosthodontists	500
Dentists, all other specialists	6,900
Number of accredited dental schools	62

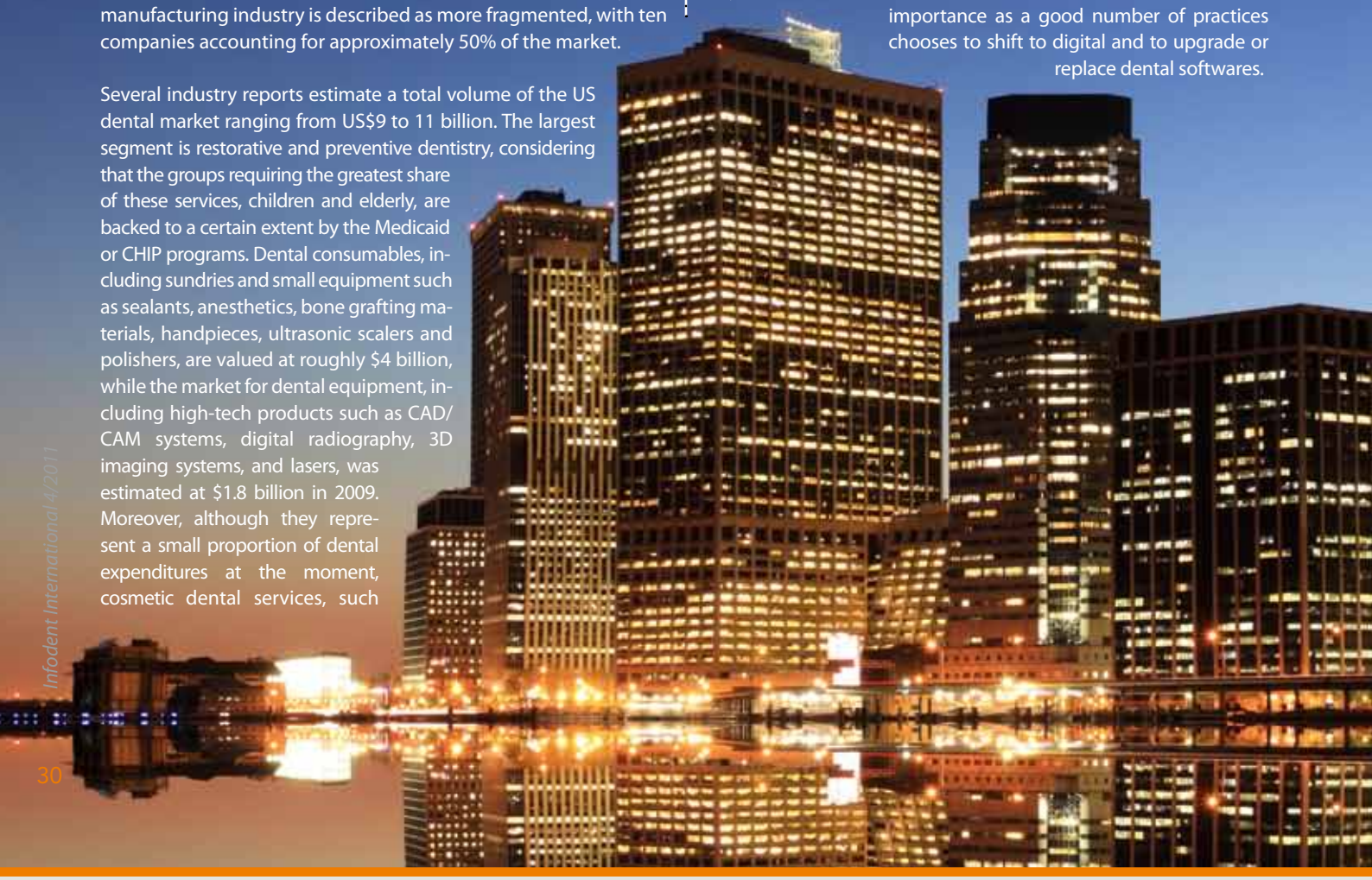
Source: ADA, US Department of Labor

According to a market analysis released by Brocair Partners, there are 120,000 office-based dental practices in the USA, which are supplied by dental distributors. The biggest dental distributors in the U.S. are Henry Schein, Inc. and Patterson Companies, Inc., holding about 40% and 32% of the market share respectively. The manufacturing industry is described as more fragmented, with ten companies accounting for approximately 50% of the market.

Several industry reports estimate a total volume of the US dental market ranging from US$9 to 11 billion. The largest segment is restorative and preventive dentistry, considering that the groups requiring the greatest share of these services, children and elderly, are backed to a certain extent by the Medicaid or CHIP programs. Dental consumables, including sundries and small equipment such as sealants, anesthetics, bone grafting materials, handpieces, ultrasonic scalers and polishers, are valued at roughly $4 billion, while the market for dental equipment, including high-tech products such as CAD/CAM systems, digital radiography, 3D imaging systems, and lasers, was estimated at $1.8 billion in 2009. Moreover, although they represent a small proportion of dental expenditures at the moment, cosmetic dental services, such as bleaching, are gaining popularity due to the increasing consciousness of a consumer base that is for the greatest part already largely educated. New technologies are making these procedures faster, less invasive and cheaper, bringing them to the reach of larger groups of the population.

The effects of recession and tighter spending on dental services continue to affect the various segments of the market, as well as the behaviours of dental practices, as it happens for dental implant procedures. Many patients opt for less expensive alternatives, such as crowns and bridges, so the volume of dental implant products purchased has declined in the latest years. However, the demand for dental services is expected to be supported in the long term from the expansion of medical coverage envisaged by the health reform. Furthermore, US population is growing and the elderly segment is one of the fastest growing groups. According to the US Department of Labor, these demographic trends will increase the demand for dental care since many members of the baby-boom generation are going to be in need of treatment in the coming years, and elderly people are more likely to retain their teeth and require dental care.

According to a report by Millennium Research Group, although the modest economic growth expected for the next few years, the dental market could benefit from technological innovations and improved training for practitioners for minimally invasive procedures that offer improved aesthetic results with shorter treatment lengths. Moreover, automated and digital technologies that increase laboratory production capabilities and digital dental imaging are gaining importance as a good number of practices chooses to shift to digital and to upgrade or replace dental softwares.



Selected dental trade figures, 2010

Commodity Group	Import value, US$ million	Export value, US$ million
Preparations for oral hygiene	84,4	203,9
Dental floss	81	27,9
Dental drill engines	71,4	37
Dental instruments/apparatuses, excl. drills	573,7	421,3
Artificial teeth	95,9	137,1
Dental fittings excl. teeth	261,6	396
X-ray apparatuses for dental uses	157,9	98

Source: United Nations Commodity Trade Statistics Database

Regulations affecting the Dental Market

FDA is responsible for the registration of any dental device or product to be sold in the USA territory, and it does not recognize any other certification. The marketing process of a medical device depends on its classification: FDA can either "clear" a medical device after reviewing a Premarket Notification known as 510(k), or "approve" it after reviewing a premarket approval (PMA) application. Classification of medical devices is based on three risk levels: Class I, Class II and Class III, the highest risk class.

A small number of Class I devices and almost all Class II medical (or dental) devices requiring clearance for US market entry must follow a pre-market notification procedure known as 510(k), from the number of the related section of the Federal Food, Drug and Cosmetic Act. A 510(k) submission is based on comparison of the new device with devices already legally marketed in the USA. Medical device manufacturers are required to submit a 510(k) if they intend either to introduce a device for commercial distribution in the USA for the first time, or to reintroduce a device that has been substantially modified. Class I devices and some Class II devices that do not require FDA review are considered "510(k) exempt", but they are still subject to general controls on suitability for intended use, packaging and labeling, establishment registration and device listing forms and manufacturing quality system, except for a few class I devices that are subject only to complaint files and general recordkeeping requirements.

Class III medical devices need instead a Pre-Market Approval, that requires the submission of clinical data in support of the application. For high risk devices introduced after 1990 manufacturers are required to have procedures for post-market surveillance, Quality Systems (QS), also known as Good Manufacturing Practices (GMPs) and Medical Device Reporting (MDR) for adverse events in place.

Besides marketing clearance, basic Pre-market Requirements are labeling in accordance with FDA regulation, establishment registration with the FDA and medical device listing in the FDA Unified Registration and Listing System (FURLS).

FDA is responsible for the registration of any dental device or product to be sold in the USA territory, and it does not recognize any other certification.

In particular, foreign manufacturers that export electronic products that emit radiation to the USA are subject to the requirements of the FD&C Act, Subchapter C - Electronic Product Radiation Control, including performance standards, labeling, and submission of radiation safety product reports. Importers may submit these reports on behalf of manufacturers.

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements.

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements. The importer submits entry information to the local CBP district office, or asks "filers", domestic customhouse brokers, to fill these forms electronically on its behalf. Filers have access to the Operational and Administrative Systems for Import Support (OASIS), the FDA computerized import system serving as interface between FDA and the CBPs Automated Commercial System (ACS). When an entry is filed with CBP, a copy is also provided to the local FDA district office which determines if the product complies with FDA requirements. FDA may detain a product that appears to be out of compliance with the FD&C Act, and the FDA office will issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee, who is then entitled to an informal hearing to submit evidence that the product is in compliance. If he fails submitting such evidence, FDA will issue another "Notice of FDA Action" refusing admission to the product, that has to be exported or destroyed within 90 days, under penalty of an assessment for liquidated damages for up to 3 times its value.

Entering the US market

Some important factors may help to correctly approach the US market.

1. Market Analysis: it is essential to understand that US market requires simple, safe, efficient, cost-effective solutions. This is particularly true for the medical and dental domain. A clear understanding of US pricing structure is part of this analysis.

2. Pre-market Approval: obtaining FDA clearance can be a relatively complicated process, companies entering the market for the first time are advised to get support from a third party that can help dealing with the legal requirements.

3. Building up the distribution/sales network: accurate research and selection of dealers is essential, but not enough. Post-sales assistance and the provision of adequate promotional material and training are equally important. The US market requires an in-country representation and a well structured logistic management, as the territory is too wide for just one or two distributors.

Sources:

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AmeriCares - www.AmeriCares.org
Kaiser Family Foundation - www.kff.org
Centers for Disease Control and Prevention - www.cdc.gov
US Department of Health and Human Services - www.hhs.gov
American Dental Association - www.ada.org
National Association of Dental Plans - www.nadp.org
Food and Drug Administration - www.fda.gov