



If you would like to share news or information with our readers, please send the unique stories, business

news organization events, and school news to us including your name and phone number in case more information is needed.

For news and information consideration, please send to News@scdaily.com or contact

John Robbins 281-965-6390
Jun Gai 281-498-4310

Publisher: Wea H. Lee
President: Catherine Lee
Editor: John Robbins

Address: 11122 Bellaire Blvd., Houston, TX 77072
E-mail: News@scdaily.com



Inside C2

Southern DAILY

Make Today Different

Southern Daily News is published by Southern News Group Daily

Sunday, January 01 2023

Congressional report: U.S. FDA broke own protocols in approving Biogen Alzheimer's drug

WASHINGTON, Dec 29 (Reuters) - The U.S. Food and Drug Administration failed to adhere to its own guidance and internal practices during the approval process for Biogen's (BIIB.O) Alzheimer's drug Aduhelm, which was "rife with irregularities," a congressional report showed on Thursday.

The FDA's interactions with Biogen were "atypical" and did not follow the agency's documentation protocol, according to a staff report on the findings of an 18-month investigation conducted by two House of Representatives committees into the drug's regulatory review, approval, pricing, and marketing.

The FDA approved Aduhelm in June 2021 under an accelerated approval pathway over the objections of its panel of outside advisers, who did not believe data definitively proved the drug's benefit to patients.

It was authorized based on evidence that it could reduce brain plaques, a likely contributor to Alzheimer's, rather than proof that it slowed progression of the lethal mind-wasting disease.

The Medicare program restricted its coverage, which has led to severely limited use of the Biogen drug.

China COVID deaths accelerate to 9,000 a day - UK research firm Airfinity
Biogen set an "unjustifiably high" price by initially setting Aduhelm's price at \$56,000 per year despite a lack of demonstrated clinical benefit in a broad patient population, the report said, adding that the company's own internal projections showed it expected the drug to be a burden to Medicare and costly to patients.

"The findings in this report raise serious concerns about FDA's lapses in protocol and Biogen's disregard of efficacy and access in the approval process for Aduhelm," the report, prepared by the staffs of the House Committee on Oversight and Reform and House Committee on Energy and Commerce, concluded.

The agency should ensure that all substantive interactions with drug sponsors are properly memorialized, establish a protocol for joint briefing documents with drug sponsors, and update its industry guidance on the developments and review of new Alzheimer's Drugs, the report recommended.

Biogen and other drugmakers should communicate to the FDA any concerns over safety and efficacy to the FDA as well as take value and patient access into consideration when setting prices, the report said.

An FDA spokesperson said the FDA's decision to approve Aduhelm was based on scientific evaluation of the data contained in the application.

He pointed to the FDA's internal review finding its staff's interactions with Biogen appropriate.

"It is the agency's job to frequently interact with companies



in order to ensure that we have adequate information to inform our regulatory decision-making. We will continue to do so, as it is in the best interest of patients," he said, adding that the agency will continue to use the accelerated approval pathway whenever appropriate.

The FDA has already begun implementing some of the report's recommendations, the spokesperson said.

"Biogen stands by the integrity of the actions we have taken," the Cambridge, Mass.-based biotech company said in an emailed statement.

"As stated in the congressional report, an (FDA) review concluded that, 'There is no evidence that these interactions with the sponsor in advance of filing were anything but appropriate in this situation,'" Biogen said.

Documents obtained by the committees show that FDA staff and Biogen held at least 115 meetings, calls, and email exchanges over a 12-month period starting July 2019.

The total number of meetings is unknown because the FDA failed to keep a clear record of informal meetings and interactions between its staff and Biogen representatives. The investigation identified an additional 66 calls and email exchanges that were not memorialized.

The FDA inappropriately collaborated with Biogen on a joint briefing document for the Peripheral and Central Nervous System (PCNS) Advisory Committee, the report said, with FDA and Biogen staff working closely for months ahead of the Nov. 6, 2020 meeting to prepare the document, which failed to adequately represent differing views within the agency.

"Using a joint briefing document afforded Biogen advance insight into FDA's responses and direct guidance from the agency in drafting the company's own sections. For example, in an exchange of the draft briefing document on October 9, 2020, FDA staff asked Biogen to move a paragraph drafted by the agency into Biogen's section of the memorandum—a change reflected when the document was finalized," the report made public to media organizations said.

When none of the advisory panel members voted to approve Aduhelm, the FDA pivoted to using its accelerated approval pathway - typically used for rare diseases or small patient populations that lack access to effective treatments - despite having considered the drug under the traditional approval pathway for nine months, the report said.

It did so on a substantially abbreviated timeline, approving it after three weeks of review, and for a broad label indication of "people with Alzheimer's disease" that was unsupported by clinical data, the report said.

Internal documents obtained by the investigation showed that Biogen accepted the indication despite its own reservations over the lack of evidence Aduhelm could help patients at disease stages outside of its clinical trials.

休士頓黃頁

SOUTHERN CHINESE DAILY NEWS



美南報業電視傳媒集團
SOUTHERN NEWS GROUP

走進歷史 • 策劃將來



休斯頓最具影響力的中文黃頁

T 281-498-4310
F 281-498-2728

11122 Bellaire Blvd Houston, TX 77072

ad@scdaily.com
www.scdaily.com

WEA LEE'S GLOBAL NOTES

12/31/2022

Thought of the past year

As the last page of this year's calendar passes we welcome the arrival of the 2023 new year. Life likes a train that can only walk forward. The days are a journey without ending. Tears and sweat are intertwined There are filled with laughter and sadness.

Last year there was a war around us, banks raised interest rates, prices soared, and the epidemic was still full of disaster and suffering. Messi took back the world championship for Argentina, but could not able to help his compatriots to live and struggle under poverty. Donald Trump's legal issue may break his presidential dream. Tesla's boss Musk wanted to become a media tycoon and make himself at the crisis.

Personally, We are very grateful to meet many of our old friends in our house to celebrate the 20th birthday of the International Trade center.

We media person we always stand at the forefront line to serve everyone forever.



Wea H. Lee
Wealee@scdaily.com

Chairman of International District Houston Texas
Publisher Southern Daily Wea H. Lee

Southern News Group Chairman / CEO
Chairman of International Trade & Culture Center
Republic of Guiana Honorary consul at Houston Texas



Southern DAILY Make Today Different

Pictures of the year



A view shows residential buildings destroyed during Russia's invasion of Ukraine in the town of Irpin, outside Kyiv, Ukraine, April 29. REUTERS/Valentyn Ogirenko



People walk at the art installation "Nowhere" by Gregory Orekhov at the Malevich park near the village of Razdory, outside Moscow, Russia February 6, 2022. REUTERS/Maxim Shemetov



Fish farm cultivator Ioannis Ouzounoglou collects fish that died from low temperatures, at his fish farm in Richo lagoon, in Igoumenitsa, Greece, January 26. REUTERS/Giannis Floulis



A view shows residential buildings destroyed during Russia's invasion of Ukraine in the town of Irpin, outside Kyiv, Ukraine, April 29. REUTERS/Valentyn Ogirenko



The Parthenon temple is seen atop the Acropolis hill, during heavy snowfall in Athens, Greece, January 24. REUTERS/Alkis Konstantinidis



People participate in a yoga class on the roof of a building to celebrate the summer solstice, on International Yoga Day, in Caracas, Venezuela June 21. REUTERS/Leonardo Fernandez Viloria

Southern DAILY Make Today Different

BUSINESS

Happy New Year 2023!!

Here's What Happened In 2022 A Photo Essay Of World Events

Compiled And Edited By John T. Robbins, Southern Daily Editor



Key Point

The year 2022 has been full of rapid and unexpected changes. From severe flooding in Pakistan to the death of Queen Elizabeth II, the following pictures cover major news events from the past 12 months.

2022 has been a year like no other. Economic, environmental and geopolitical turmoil have defined the past 12 months, in a year that saw the death of the British monarch Queen Elizabeth II and the invasion of Ukraine by Russia.

1. Inflation surges around the world



Inflation has been unusually high in many countries around the world in 2022.

Inflation has been unusually high in countries around the world in 2022. Price increases in the US peaked at more than 9.1% in June, and at 11.1% in the UK in October. This has resulted in a cost-of-living crisis,

with many families, even in some of the world's wealthiest nations, being forced to choose between eating or heating this winter.

2. The Omicron coronavirus variant spreads



The Omicron variants were a highlight in the year 2022.

Image: REUTERS/Jeenah Moon

The highly transmissible Omicron variant of COVID-19 spread around the world this year. Two Omicron "cousins" have also recently been named by the UK Health Security Agency, as the virus continues to mutate.

DISCOVER

3. Russia invades Ukraine



Russia invaded Ukraine on 24 February, 2022. Image: REUTERS/Shannon Stapleton

Russia invaded Ukraine on 24 February, leading to global crises for both food and energy, as well as displacing millions of people.

4. U.S. Supreme Court overturns abortion rights



The vote for abortion rights was 5-4 to overturn the landmark 1973 Roe vs Wade ruling, on 24 June, 2022. Image: REUTERS/Michael A. McCoy

In a controversial ruling on 24 June, the US Supreme Court revoked women's constitutional right to abortion, restoring the ability of individual states to determine a woman's reproductive rights.

5. Record-breaking heatwaves worldwide



Climate change has led to many record-breaking temperatures around the world. From runways melting to devastating wildfires, no country was safe from the extreme levels of heat experienced this year.

6. Droughts around the world



The summer of 2022 produced Europe's worst drought in 500 years. Image: REUTERS/Susana Vera

This summer produced Europe's worst drought in 500 years, with two-thirds of the continent experiencing some sort of extreme heat warning. In China, factories were forced to shut down in August due to decreased water levels around the Yangtze river basin, which curbed electricity generation at hydropower plants.

7. Massive flooding in Pakistan



A flooded highway in Sehwan, Pakistan. Image: REUTERS/Akhtar Soomro

Flooding in Pakistan from June to August killed more than 1,391 people and caused an estimated \$30 billion in damage as houses, crops and key infrastructure were swept away.

8. Queen Elizabeth II passes away

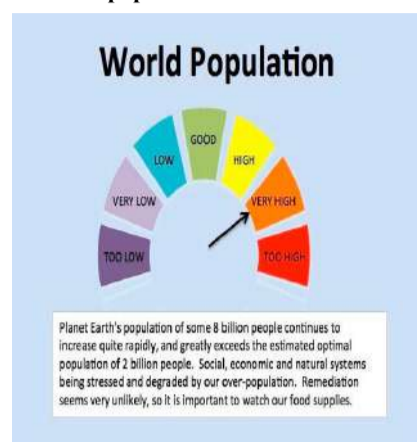


Queen Elizabeth II died at Balmoral

Castle in Scotland on 8 September, 2022. Image: Tristan Fewings/Pool via REUTERS

Queen Elizabeth II died at Balmoral Castle in Scotland on 8 September and was succeeded by her eldest son, King Charles III. She died at 96 years of age after 70 years on the throne, making her the world's second longest-ever reigning monarch

9. World population exceeds 8 billion



On 15 November 2022, the world surpassed 8 billion people. Image: REUTERS/Jon Nazca

The world reached its first landmark of 1 billion people in 1803. Over 200 years later, on 15 November 2022, the world surpassed 8 billion people.

10. COP27's 'loss and damage' fund for vulnerable countries



One of the many issues discussed at the UN summit was 'loss and damage'. Image: REUTERS/Mohamed Abd El Ghany

The fund agreed at the COP27 summit will support poor countries that are being heavily impacted by climate change, despite their historically low emissions. It will cover the cost of any climate-related damage that these countries cannot avoid or adapt to. (Courtesy weforum.org)

Southern DAILY Make Today Different

COMMUNITY

Highlights From The United Nations' Latest Release Of Its World Population Estimates

Key Findings From The 2022 United Nations Population Prospects Study

Compiled And Edited By John T. Robbins, Southern Daily Editor



Key Points

How many people are there in the world? How many die each year, and how many babies are born? These are key questions that we need to understand the world around us. The global population dataset is one of our most important at Our World in Data: it underpins nearly every topic we cover. The UN releases an update of its World Population Prospects every two years. Its latest release was due in 2021 but was delayed as a result of the COVID-19 pandemic. But, today – on World Population Day – the long-awaited dataset has been released. The following article highlights some of the key findings of the twenty-seventh publication of the 'World Population Prospects'.



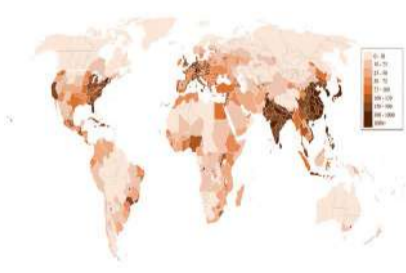
Overview United Nations July 11, 2022 Department of Economic and Social Affairs Population Division World Population Prospects 2022

The 2022 Revision of World Population Prospects is the twenty-seventh edition of official United Nations population estimates and projections that have been prepared by the Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. It presents population estimates from 1950 to the present for 237 countries or areas, underpinned by analyses of historical demographic trends. This latest assessment considers the results of 1,758 national population censuses conducted between 1950 and 2022, as well as information from vital registration systems and from 2,890 nationally representative sample surveys. The 2022 revision also presents population projections to the year 2100 that reflect a range of plausible outcomes at the global, regional and national levels.

By Hannah Ritchie, Edouard Mathieu, Lucas Rolés-Guirao and Marcel Gerber

#1. The World Population Will Pass 8 Billion At The End Of 2022

Since 1975 the world has been adding another billion people every 12 years. It passed its last milestone – 7 billion in 2011. And, by the end of 2022, it will pass another one: there will be 8 billion people in the world. While this rate of absolute growth is similar to previous decades, the growth rate continues to fall. Since 2019, the global population growth rate has fallen below 1%.



That's less than half its peak rate of growth – of 2.3% – in the 1960s. As global fertility rates continue to fall (see below), this rate will continue to fall.

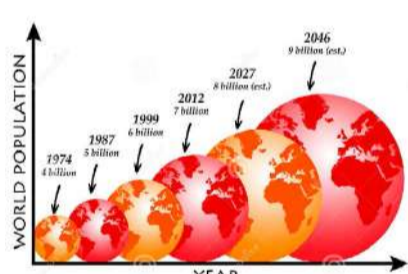
#2. The UN Estimates Around 15 Million Excess Deaths In 2020 And 2021 From The COVID-19 Pandemic

The Coronavirus (COVID-19) pandemic has had a significant impact on global population and migration trends.

We know that the confirmed death toll from COVID-19 is likely to significantly underestimate the true number of deaths because of limited testing. One way to get a better estimate of the total mortality impact of the pandemic is to look at excess mortality data. We can look at the total number of deaths and compare this to the number we expect to occur in a non-pandemic year.

In its latest population dataset, the UN estimates that in 2020, there were approximately 5 million excess deaths. In 2021, this figure was 10 million. This estimate of 15 million excess deaths over 2020 and 2021 is in line with estimates from other organizations. The Economist put its central estimate of excess deaths at 17.6 million. The World Health Organization, which is a UN organization, estimated 14.9 million excess deaths.

These death figures are highly uncertain. But what's clear is that the number of confirmed deaths – which was just 5.4 million by the end of 2021 – captures just a fraction of the true impact of the pandemic.



#3. The Global Population Is Projected To Peak At Around 10.4 Billion In 2086

The world population has increased rapidly over the last century. When will it come to an end? Previous versions of the UN World Population Prospects showed a significant slowdown in population growth, with very slow growth – almost reaching a plateau – by the end of the century. In its previous release, it projected that the world population would be around 10.88 billion in 2100, and would not yet have peaked. In this new release, the UN projects that the global population will peak before the end of the century – in 2086 at just over 10.4 billion people.1 There are several reasons for this earlier, and lower, peak. One is that the UN expects fertility rates to fall more quickly in low-income countries compared to previous revisions. It also expects less of a 'rebound' in fertility rates across high-income countries in the second half of the century.

#4. The Global Fertility Rate Has Continued To Decline To 2.3 Births Per Woman

A key determinant of the global population rate is the average number of children that women have over their lifetime – the 'fertility rate'. Fertility rates have fallen rapidly across the world in recent decades. In 1950, the average woman gave birth around 5 times. Since then, fertility rates have more than halved. In 2021, this global figure was 2.3 births per woman.



If you switch to the map tab in the interactive chart you see that most people in the world now live in countries where fertility rates are at – or below – the 'replacement level'. This is the level at which populations would stabilize or shrink over the long-term. The UN reports that two-thirds of people live in countries where the fertility rate is below 2.1 births per woman. In some high-income countries such as South Korea, Japan, Spain, or Italy, it is as low as 1.3 births per woman.

#5. Next Year India Is Expected To Take Over From China As The World's Most Populous Country

China has been the world's most populous country for decades. It is now home to more than 1.4 billion people. However, its population growth rate has fallen

significantly following a rapid drop in its fertility rate over the 1970s and 80s.

The fertility rate in India has also fallen substantially in recent decades – from 5.7 births per woman in 1950 to just 2 births per woman today. However, the rate of this decline has been slower.

Because of this, India will very soon overtake China as the most populous country in the world. The UN expects this to happen in 2023. (Courtesy https://ourworldindata.org/) For more information, go here: https://ourworldindata.org/world-population-update-2022.

Related

World Population Highlights

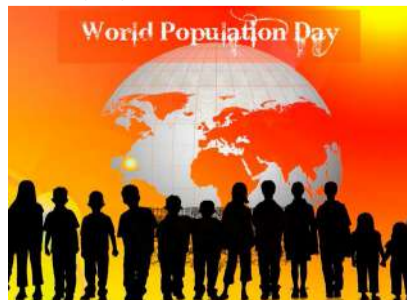
The Current World Population 7,961,890,500 TOP 20 LARGEST COUNTRIES BY POPULATION

1	China	1,450,762,207	2	India	1,408,316,238	3	U.S.A.	335,015,755
4	Indonesia	279,569,569	5	Pakistan	230,046,479	6	Brazil	215,692,458
7	Nigeria	217,184,939	8	Bangladesh	168,114,251	9	Russia	146,062,225
10	Mexico	131,769,917	11	Japan	125,692,247	12	Ethiopia	121,119,605
13	Philippines	112,649,389	14	Egypt	106,448,353	15	Vietnam	99,162,605
16	D.R. Congo	95,528,891	17	Turkey	86,236,933	18	Iran	86,251,924
19	Germany	84,334,434	20	Thailand				

World Population: Past, Present, and Future

At the dawn of agriculture, about 8000 B.C., the population of the world was approximately 5 million. Over the 8,000-year period up to 1 A.D. it grew to 200 million (some estimate 300 million or even 600, suggesting how imprecise population estimates of early historical periods can be), with a growth rate of under 0.05% per year.

A tremendous change occurred with the industrial revolution: whereas it had taken all of human history until around 1800 for world population to reach one billion, the second billion was achieved in only 130 years (1930), the third billion in 30 years (1960), the fourth billion in 15 years (1974), and the fifth billion in only 13 years (1987).



- During the 20th century alone, the population in the world has grown from 1.65 billion to 6 billion.
- In 1970, there were roughly half as many people in the world as there are now.
- Because of declining growth rates, it will now take over 200 years to double again.

Population Growth Rate

Population in the world is, as of 2020, growing at a rate of around 1.05% per year (down from 1.08% in 2019, 1.10% in 2018, and 1.12% in 2017). The current average population increase is estimated at 81 million

people per year.

Annual growth rate reached its peak in the late 1960s, when it was at around 2%. The rate of increase has nearly halved since then, and will continue to decline in the coming years.

World population will therefore continue to grow in the 21st century, but at a much slower rate compared to the recent past. World population has doubled (100% increase) in 40 years from 1959 (3 billion) to 1999 (6 billion). It is now estimated that it will take another nearly 40 years to increase by another 50% to become 9 billion by 2037.



The latest world population projections indicate that world population will reach 10 billion people in the year 2057.

World Population Forecast (2020-2050) 10 Billion (2057) The United Nations projects world population to reach 10 billion in the year 2057.

9 Billion (2037) World population is expected to reach 9 billion in the year 2037.

8 Billion (2023) World population is expected to reach 8 billion people in 2023 according to the United Nations (in 2026 according to the U.S. Census Bureau).

7.96 Billion (2022) The current world population is 7.96 billion as of July 2022 [1] according to the most recent United Nations estimates elaborated by Worldometer. The term "World Population" refers to the human population (the total number of humans currently living) of the world.



7 Billion (2011) According to the United Nations, world population reached 7 Billion on October 31, 2011.

The US Census Bureau made a lower estimate, for which the 7 billion mark was only reached on March 12, 2012.

6 Billion (1999) According to the United Nations, the 6 billion figure was reached on October 12, 1999 (celebrated as the Day of 6 Billion). According to the U.S. Census Bureau instead, the six billion milestone was reached on July 22, 1999, at about 3:49 AM GMT. Yet, according to the U.S. Census, the date and time of when 6 billion was reached will probably change because the already uncertain estimates are constantly being updated. (Courtesies https://www.worldometers.info)