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Research Article

AUDIT OF USFDA APPROVALS FOR 2022 FROM THE PERSPECTIVE OF INNOVATION

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ABSTRACT

Objectives: The United States of America (USA) is having a unique place in global innovation within the health-care sector due to the presence of a large number of research-oriented biopharmaceutical companies, contract research organizations, and government research agencies. The aim of this study was to analyze the U.S. Food and Drug Administration (USFDA) approvals for 2022 to increase the awareness among health-care professionals for better clinical decisions.

Methods: This was an observational study conducted using online database of USFDA which is accessible freely by the public. The USFDA approvals for 2022 were assessed for new molecular entities (NMEs) including their source and therapeutic area, new indications (NIs) of previously approved drugs, new label extensions (NLEs) of previously approved drugs, new routes of administration (NRAs) of previously approved drugs, and new dosage forms (NDFs) of previously approved drugs. The data obtained were arranged in the tabular form using Microsoft Office Excel 2007. Descriptive statistics was used for analysis.

Results: Out of 118 USFDA approvals considered for this study, 25.4% of them were given for NMEs, 27.9% approvals were given for NIs, 33.8% approvals were given for NLEs, 6.7% approvals were given for NRAs, and the remaining 5.9% approvals were given for NDFs. 14 out of 30 NMEs were biologicals and 43.3% of NMEs were indicated for different types of cancer.

Conclusion: The USFDA continued to adopt several approaches such as Fast Track process, breakthrough therapy process, accelerated approval process, and priority review process to encourage the research-based biopharmaceutical companies involved in the development of therapeutic options for patients suffering from common as well as rare diseases. More emphasis was given to the approvals of anticancer drugs given the limited options available to treat the cancer in advanced or metastatic stages. However, a lack of discovery and development of antimicrobials with novel mechanism of actions to combat resistance is a cause of concern.

Keywords: Innovative research, New Molecular Entities, USFDA, Healthcare Professionals.

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INTRODUCTION

Clinical research is a branch of medical science related to the effectiveness and testing of medications, diagnostic products, medical devices, and treatment procedures for human use [1]. Innovative clinical research aims to find a solution to unanswered questions arising in clinical practice and in doing so involves the participation of animals/human beings as the experimental tool [2]. Few examples of innovative clinical research include gene therapy (Etranacogene Dezaparvovec-drlb) for the treatment of adults with hemophilia B and monoclonal antibody (Teplizumab-mzwv) to delay the onset of Stage 3 type 1 diabetes (T1D). [3,4]. Innovative clinical research also implies to clinical trials conducted to find out new indication or new route of administration or new dosage of already permitted drug formulation [2]. An example of this type is development of sublingual film of Dexmedetomidine for acute treatment of schizophrenia or bipolar disorder-associated agitation.

Innovative clinical research is usually carried out by pharmaceutical companies, contract research organizations, and government research agencies. The United States of America (USA) is having a unique place in global innovation within the health-care sector due to the presence of a large number of these establishments. It has a large number of clinical trials registered than any other country in the world [5]. The U.S. Food and Drug Administration (USFDA's) Center for Drug Evaluation and Research (CDER) is responsible for approving new molecular entities and new therapeutic biological products before selling them by the pharmaceutical companies for their intended use in patients [6]. The Center for Biologics Evaluation and Research (CBER) of USFDA is responsible for approving the vaccines, blood and blood products, plasma derivatives, cellular and gene therapy products, etc. [7].

The CDER and CBER scrutinize everything about the drug from the study design of clinical trials to the safety and finally to the manufacturing practices to make appropriate decisions. They ensure that the medicinal products work correctly and that their health benefits outweigh known risks. These agencies also adopt several approaches such as Fast Track process, Breakthrough Therapy process, Accelerated Approval process, and Priority Review process to expedite the development of drugs that are either intended to treat patients with a life-threatening disease (for which no other therapy exists) or may demonstrate substantial improvement over available therapy [8].

Starting from suggesting various screening tests to detect health problems to follow-up management of chronic conditions such as asthma, hypertension, diabetes, and depression, primary care physician acts as a point of first contact for any medical problem that is not an emergency [9]. Due to their significant contribution in health-care sector, knowledge of recent drug approvals and new indications of the already approved drugs is necessary to make better clinical care decisions.

Given the context, this study has been taken to analyze the USFDA approvals for 2022 to increase the awareness among health-care professionals.

METHODS

It is an observational study based on the data collected from online database of USFDA which is available freely to the public [6,7]. The USFDA approvals for 2022 were assessed for,

1. New Molecular Entities (NMEs) including their source and therapeutic area
2. New Indications (NIs) of previously approved drugs
3. New Label Extensions (NLEs) of previously approved drugs
4. New Routes of Administration (NRAs) of previously approved drugs
5. New Dosage Forms (NDFs) of previously approved drugs

Exclusion criteria

1. Approvals received from other countries before USFDA
2. Vaccines, plasma-derived biologics, and diagnostic agents approved by the USFDA
3. NMEs receiving emergency use authorization (EUA) from the USFDA

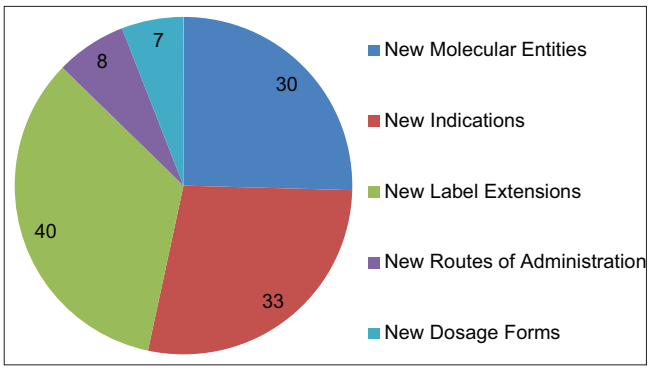

Fig. 1: Different types of USFDA approvals in 2022

Statistical analysis

Microsoft Office Excel 2007 was used for tabulation and analysis. Descriptive statistics was used for analysis.

RESULTS

A total of 118 different types of USFDA approvals for the year 2022 were considered for this study based on the predetermined methodology. Out of these, 25.4% of the approvals were given for NMEs, 27.9% approvals were given for NIs, 33.8% approvals were given for NLEs, 6.7% approvals were given for NRAs, and the remaining 5.9% approvals were given for NDFs (Fig. 1 and Tables 1-5).

Whereas out of 30 new molecular entities approved during 2022, 14 were biological and the remaining 16 were synthetic drugs. Considering the therapeutic area of approved new molecular entities, 43.3% were indicated for different types of cancer, 13.3% for neurological disorders, 10% for hematological disorders, 10% for dermatological disorders, 6.6% for endocrine disorders, and 6.6% for infectious diseases. With 3.3% each, NMEs for cardiovascular, ophthalmic, and cosmetic problems were least in number (Table 1).

DISCUSSION

The increasing trend of biopharmaceutical companies focusing on the discovery, development, and commercialization of biologics is clearly seen based on our analysis. The year 2022 has witnessed the authorization of a large number of novel drugs, similar to previous years [10-12]. Noted breakthroughs for 2022 include gene therapies for the management of bladder cancer (Nadofaragene Firadenovec-vncg), relapsed or refractory multiple myeloma (Ciltacabtagene Autoleucel) and hemophilia B (Etranacogene Dezaparvovec-drlb). Among them, gene therapy for hemophilia B is considered a significant milestone as it allows patients to produce their own factor IX, which can lower the risk of bleeding, and thereby replacing the present lifelong infusion schedules of exogenous factor IX [3]. Another groundbreaking drug approved in

Table 1: New molecular entities approved in 2022

Trade name	Active ingredient	Indications	Source	Therapeutic area
Adstiladrin	Nadofaragene Firadenovec-vncg	Bladder cancer	Biological	Oncology
Amvuttra	Vutrisiran	Amyloidosis	Synthetic	Neurology
Briumvi	Ublituximab-xiiy	Relapsed multiple sclerosis	Biological	Neurology
Camzyos	Mavacamten	Obstructive hypertrophic cardiomyopathy	Synthetic	Cardiology
Carvykti	Ciltacabtagene autoleucel	Relapsed or refractory multiple myeloma	Biological	Oncology
Daxxify	DaxibotulinumtoxinA-lanm	Glabellar lines	Biological	Cosmetology
Elahere	Mirvetuximab soravtansine-gynx	Platinum-resistant ovarian cancer	Biological	Oncology
Enjaymo	Sutimlimab-jome	Cold agglutinin disease	Biological	Hematology
Hemgenix	Etranacogene dezaparvovec-drlb	Hemophilia B	Biological	Hematology
Imjudo	Tremelimumab	Unresectable hepatocellular carcinoma	Biological	Oncology
Kimmtrak	Tebentafusp-tebn	Metastatic uveal melanoma	Synthetic	Oncology
Krazati	Adagrasib	Metastatic nonsmall cell lung cancer	Synthetic	Oncology
Lunsumio	Mosunetuzumab-axgb	Relapsed or refractory follicular lymphoma	Biological	Oncology
Lytgobi	Futibatinib	Metastatic cholangiocarcinoma	Synthetic	Oncology
Mounjaro	Tirzepatide	Type 2 diabetes	Synthetic	Endocrinology
Opdualag	Relatlimab-rmbw	Metastatic melanoma	Biological	Oncology
Pluvicto	Lutetium (177Lu) vipivotide tetraxetan	Metastatic prostatic cancer	Synthetic	Oncology
Pyrukynd	Mitapivat	Pyruvate kinase deficiency	Synthetic	Hematology
Quviviq	Daridorexant	Insomnia	Synthetic	Neurology
Rebyota	Fecal microbiota, live-jslm	Reduce recurrence of *Clostridioides difficile* infection	Biological	Infectious diseases
Rezlidhia	Olutasidenib	Relapsed or refractory acute myeloid leukemia	Synthetic	Oncology
Rolvedon	Eflapegrastim	Chemotherapy induced neutropenia	Synthetic	Oncology
Sotyktu	Deucravacitinib	Plaque psoriasis	Synthetic	Dermatology
Spevigo	Spesolimab-sbzo	Pustular psoriasis	Biological	Dermatology
Tzield	Teplizumab-mzwv	Type 1 diabetes	Biological	Endocrinology
Vabysmo	Faricimab-svoa	Wet age-related macular degeneration and diabetic macular oedema	Biological	Ophthalmology
Vivjoa	Oteseconazole	Reduce recurrence of vulvovaginal candidiasis	Synthetic	Infectious diseases
Vonjo	Pacritinib	Myelofibrosis	Synthetic	Oncology
Vtama	Tapinarof	Plaque psoriasis	Synthetic	Dermatology
Ztalmy	Ganaxolone	Cyclin-dependent kinase-like 5 deficiency disorder	Synthetic	Neurology

Table 2: New indications of previously approved drugs in 2022

Trade name	Active ingredient	New indications
Actemra	Tocilizumab	Hospitalized COVID-19 patients
Auvelity	Dextromethorphan + bupropion	Major depressive disorder
Beovu	Brolucizumab	Diabetic macular edema
Dupixent	Dupilumab	Eosinophilic esophagitis
		Prurigo nodularis
Enhertu	Trastuzumab deruxtecan	HER2-mutant metastatic nonsmall cell lung cancer
Fintepla	Fenfluramine	Lennox-gastaut syndrome
Imfinzi	Durvalumab	Advanced biliary tract cancer in combination with gemcitabine and cisplatin
		Unresectable hepatocellular carcinoma in combination with tremelimumab
Keytruda	Pembrolizumab	Advanced endometrial carcinoma
Krystexxa	Pegloticase	Uncontrolled gout in combination with methotrexate
Kymriah	Tisagenlecleucel	Relapsed or refractory follicular lymphoma
Linparza	Olaparib	Germline BRCA-mutated HER2-negative high-risk early breast cancer
Libtayo	Cemiplimab-rwlc	Advanced nonsmall cell lung cancer
Myfembree	Relugolix + estradiol + norethindrone acetate	Moderate to severe pain associated with endometriosis
Olumiant	Baricitinib	Hospitalized COVID-19 patients
		Alopecia areata
Opdivo	Nivolumab	Resectable nonsmall cell lung cancer
Opzelura	Ruxolitinib	Vitiligo
Pedmark	Sodium thiosulfate	Cisplatin induced ototoxicity
Pemazyre	Pemigatinib	Myeloid/lymphoid neoplasms with FGFR1 rearrangement
Retevmo	Selpercatinib	Metastatic solid tumors with RET gene fusion
Rinvoq	Upadacitinib	Moderate to severe atopic dermatitis
		Moderate to severe ulcerative colitis
		Active ankylosing spondylitis
Skyrizi	Risankizumab	Moderate to severe crohn's disease
Tafinlar	Dabrafenib	BRAF V600E solid tumors in combination with trametinib
Tecentriq	Atezolizumab	Advanced alveolar soft part sarcoma
Terlivaz	Terlipressin	Hepatorenal syndrome
Ultomiris	Ravulizumab	Myasthenia gravis
Vijoice	Alpelisib	PIK3CA-related overgrowth spectrum
Vonvendi	Von willebrand factor	Severe type 3 von willebrand disease
Vraylar	Cariprazine	Major depressive disorder
Xalkori	Crizotinib	ALK-positive inflammatory myofibroblastic tumors

HER2: Human epidermal growth factor receptor 2, RET: Rearranged during transfection, BRCA: Breast cancer gene, ALK: Anaplastic lymphoma kinase, FGFR1: Fibroblast growth factor receptor 1

Table 3: New label extensions of previously approved drugs in 2022

Trade name	Active ingredient	New label extensions
Adcetris	Brentuximab vedotin	Untreated high risk classical hodgkin lymphoma in children aged 2 years and older
Benlysta	Belimumab	Active lupus nephritis in children aged 5–17 years
Brexafemme	Ibrexafungerp	Reduction of recurrent vulvovaginal candidiasis
Breyanzi	Lisocabtagene maraleucel	Large B-cell lymphoma patients
		Refractory to/relapsed after first-line chemoimmunotherapy
		Not eligible for hematopoietic stem cell transplant due to comorbidities or age
Cabenuva	Cabotegravir, rilpivirine	Once-in-2-month dosing for virologically suppressed HIV-1 in adults
		Optional "Oral Lead-In" with cabotegravir and rilpivirine tablets before starting parenteral formulation
Caplyta	Lumateperone	Dose reduction with
		Moderate to strong CYP3A4 inhibitors
		Moderate to severe hepatic impairment
CellCept	Mycophenolate mofetil	Prophylaxis of organ rejection in pediatric recipients of allogenic heart and allogeneic liver transplants aged 3 months and older
Dupixent	Dupilumab	Moderate to severe atopic dermatitis in children aged 6 months–5 years
Enhertu	Trastuzumab deruxtecan	Metastatic HER2-positive breast cancer patients
		Metastatic HER2-low breast cancer
Evrysdi	Risdiplam	Spinal muscular atrophy in infants under 2 months old
Firdapse	Amifampridine	Lambert-eaton myasthenic syndrome in children aged 6 years and older
Imbruvica	Ibrutinib	Chronic graft-versus-host disease in children aged 1 year and older
Imcivree	Setmelanotide	Obesity in children aged 6 years and older with bardet-biedl syndrome
Imfinzi	Durvalumab	Stage IV (metastatic) nonsmall cell lung cancer in combination with tremelimumab plus platinum-based chemotherapy
Jardiance	Empagliflozin	Management of heart failure in adults regardless of left ventricular ejection fraction
Mirena	Levonorgestrel	Prevent pregnancy up to 8 years
Nubeqa	Darolutamide	mHSPC in combination with docetaxel
Opdivo	Nivolumab	First-line treatment of metastatic esophageal squamous cell carcinoma
		In combination with fluoropyrimidine- and platinum-containing chemotherapy (or)
		In combination with ipilimumab

(Contd...)

Table 3: *(Continued)*

Trade name	Active ingredient	New label extensions
Orkambi	Lumacaftor + ivacaftor	Cystic fibrosis in children aged 12–<24 months
Oxlumo	Lumasiran	Primary hyperoxaluria type 1 to lower plasma oxalate levels in patients with severe renal impairment, including those on hemodialysis
Qelbree	Viloxazine	Attention deficit hyperactivity disorder in adult patients aged 18 and older
Qsymia	Phentermine + topiramate	Obesity in children aged 12 years and older
Rinvoq	Upadacitinib	Active nonradiographic axial spondyloarthritis in adults
Rylaze	Asparaginase erwinia chrysanthemi-rywn	Monday/wednesday/friday intramuscular dosing schedule for adult and pediatric patients with acute lymphoblastic leukemia or lymphoblastic lymphoma
Stelara	Ustekinumab	Active psoriatic arthritis in children aged 6 years and older
Tibsovo	Ivosidenib	Newly diagnosed isocitrate dehydrogenase-1 mutated acute myeloid leukemia in adults in combination with azacitidine
Triumeq PD	Abacavir + dolutegravir + lamivudine	Management of HIV-1 in children weighing>25 kg
Tymlos	Abaloparatide	Osteoporosis in men at high risk of fracture
Veklury	Remdesivir	Nonhospitalized patients at high risk of COVID-19 disease progression COVID-19 patients under 12 years of age
Vemlidy	Tenofovir alafenamide	Chronic hepatitis B virus infection in children aged 12 years and older
Wegovy	Semaglutide	Obesity in children aged 12 years and older
Xofluza	Baloxavir marboxil	Treat and prevent influenza in children aged 5 years and older
Yescarta	Axicabtagene ciloleucel	Use of prophylactic corticosteroids across all approved indications of yescarta Refractory or relapsed large B-cell lymphoma to first-line chemoimmunotherapy in adults

mHSPC: Metastatic hormone-sensitive prostate cancer

Table 4: New routes of administration of previously approved drugs in 2022

Trade name	Active ingredient	New routes of administration
Adlarity	Donepezil	Transdermal patch for management of dementia in alzheimer's disease
Furoscix	Furosemide	Subcutaneous formulation for ambulatory treatment of congestion due to fluid overload in patients with NYHA class II/III chronic heart failure
Igalmi	Dexmedetomidine	Sublingual film for acute treatment of schizophrenia or bipolar disorder-associated agitation
Iheezo	Chloroprocaine	Ophthalmic formulation for ocular surface anesthesia
Radicava ORS	Edaravone	Oral suspension for the treatment of amyotrophic lateral sclerosis
Tpoxx	Tecovirimat	Intravenous formulation for the treatment of smallpox
Xelstrym	Dextroamphetamine	Transdermal patch for the treatment of attention-deficit hyperactivity disorder
Zoryve	Roflumilast	Topical formulation for the treatment of plaque psoriasis

NYHA: New York Heart Association

Table 5: New dosage forms of previously approved drugs in 2022

Trade name	Active ingredient	New dosage forms
Calquence	Acalabrutinib	Tablet formulation for patients with chronic lymphocytic leukaemia, small lymphocytic lymphoma and for relapsed or refractory mantle cell lymphoma
Caplyta	Lumateperone	Dosage strengths 10.5 mg and 21 mg capsules for the treatment of depression associated with bipolar I or bipolar II disorders
Hyftor	Sirolimus	Topical gel containing 0.2% of sirolimus for the treatment of facial angiofibroma associated with tuberous sclerosis complex
Imbruvica	Ibrutinib	Oral suspension for the treatment of pediatric patients 1 year and older with chronic graft-versus-host disease
Sezaby	Phenobarbital sodium	Powder for intravenous injection for the treatment of neonatal seizures in term and preterm infants
Tyvaso DPI	Treprostinil	Dry powder inhaler for treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease to improve exercise ability
Zonisade	Zonisamide	Oral suspension for the treatment of partial seizures in patients aged 16 years and older

2022 is a monoclonal antibody, Teplizumab-mzwv. It is considered to be the first disease-modifying therapy in T1D, where it has shown to delay the onset of Stage 3 T1D in adult and pediatric patients aged 8 years and older with Stage 2 T1D by 25 months [4]. Patients who progress to Stage 3 T1D eventually require lifelong insulin injections.

Our study is in full agreement with the number of drugs approved for cancer during the previous years [12]. 14 out of 30 new molecular entities approved in 2022 were for the management of most challenging cancers (unresectable and metastatic) with limited treatment options. Similar numbers were observed for repurposed drugs. In 2022, USFDA approved 14 new indications in oncology for existing anticancer drugs. Among others, drugs repurposed for COVID19 (Tocilizumab and Baricitinib), major depressive disorder (dextromethorphan plus bupropion), vitiligo (Ruxolitinib), cisplatin-induced ototoxicity (sodium thiosulfate), hepatorenal syndrome (Terlipressin), and myasthenia gravis (Ravulizumab) are noteworthy. Drug candidates for repurposing have the advantage of requiring fewer supporting studies as the new indication is built on already available safety, pharmacokinetic, and manufacturing data [13]. This will result in shorter timelines in getting approvals from regulatory agencies and reduced costs.

With the label extensions approved by the USFDA in 2022, therapeutic options which were part of standard care for adults for so many years are now accessible to young patients as well. Prominent among them were the approvals given for brentuximab, belimumab, mycophenolate, dupilumab, risdiplam, ibrutinib, remdesivir, baloxavir, and Fixed-

dose combination of lumacaftor plus ivacaftor to manage conditions in children with limited treatment options available to date. Treating children early in life is critically important in some of the devastating diseases such as cystic fibrosis [14], because early treatment has the potential to slow the disease progression.

Innovative dosage forms or delivery systems may improve drug efficacy and tolerability, or increase convenience for the patients [15,16]. In 2022, USFDA approved a sublingual film of dexmedetomidine for acute treatment of schizophrenia or bipolar disorder-associated agitation, which is usually managed with drugs given through parenteral route. Another significant approval from USFDA includes an oral suspension of ibrutinib for the treatment of children aged 1 year and older with chronic graft-versus-host disease. This dosage form is convenient for the children aged up to 5 years who have difficulty in swallowing tablets.

Development of a new drug is extremely challenging and despite the obstacles that COVID-19 has posed in 2020 and continues to pose a serious threat to public health, 2022 has been an excellent year for pharmaceutical sector in terms of new drug applications accepted by the USFDA. The authors of this study hope that, with the publication of "New Drugs and Clinical Trials 2019" rules by the Union Ministry for Health and Family Welfare, New Delhi, India, the pace of innovative clinical research may increase in India as well [2]. This study might help the primary care physicians to get well versed with the latest approvals from the USFDA.

CONCLUSION

The USFDAs commitment to bring newer treatment options to address the patient needs with an established track record of safety and efficacy of the new as well as the previously approved molecules is noticed in our analysis. Various approaches have been utilized continuously by the USFDA to encourage the research based biopharmaceutical companies involved in the development of therapeutic options for patients suffering from rare diseases such as cyclin-dependent kinase-like 5 deficiency disorder. More emphasis was given to the approvals of anticancer drugs given the limited options available to treat the cancer in advanced or metastatic stages. There has been a slow but steady progress in drug approvals for lifestyle diseases such as obesity and diabetes. On the contrary, lack of discovery and development of antimicrobials with novel mechanism of actions to combat resistance is a cause of concern. This trend is harmful to the developing countries like India, where the burden of infectious diseases is high.

Limitations

We did not analyze the biosimilars and generic medicines approved by the USFDA in 2022 due to a lack of innovative research involved in the development of these drugs.

AUTHORS' CONTRIBUTION

All the authors have contributed equally.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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Nil.

ETHICAL APPROVAL

Not required.

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