

**Reconnect & Rediscover:**  
A Convening Pediatric Experts  
and Advocates  
Oct. 2-4, 2021

National Association of  
Pediatric Nurses  
& 2021 National Association of Pediatric Nurse Practitioners

Experts in pediatrics, Advocates for children. 1

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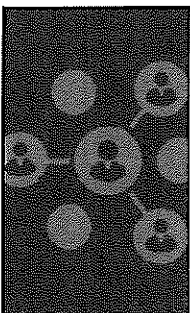
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**2021 Update on Pediatric  
Pharmacology**  
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Woodcreek Mary Bridge Urgent Care  
Saint Martin's University

National Association of  
Pediatric Nurse Practitioners  
& 2021 National Association of Pediatric Nurse Practitioners

Experts in pediatrics, Advocates for children. 2

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**Disclosure**

- Teri Moser Woo, PhD, RN, CNL, CPNP, FAANP has no relevant financial relationships to disclose
- Co-author of *Pharmacotherapeutics for Advanced Practice Registered Nurses 4<sup>th</sup> Ed. (2016) & 5<sup>th</sup> Ed. (2019)*

National Association of  
Pediatric Nurse Practitioners

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## Objectives

- Review new pediatric drugs on the market in 2020/2021
- Advances in pediatric prescribing knowledge
- Discuss current issues impacting pediatric prescribing
- Discuss pediatric drugs on the horizon



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## Challenges with new Drug development for children

- Developing pediatric-friendly formulations
  - Suspensions, solutions, quick dissolve tablets
- Drug testing on a vulnerable population
- Relatively rare disorders
  
- WHO list of Essential Medicines in children

WHO, 2019



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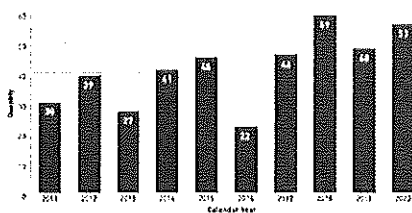
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CDER's Annual Novel Drug Approvals: 2011 - 2020

Source: CDER's Annual Report to Congress: Pediatric Drug Development and Approval: A Decade of Progress (2021)



FDA, 2021



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### New ADHD drugS

- Serdexmethylphenidate and dexamethylphenidate (Azstarys)
  - 30% dexmethylphenidate and 70% serdexmethylphenidate
- viloxazine (Qelbree)
  - norepinephrine reuptake inhibitor
  - extended-release capsules



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### New Head lice treatment

- Abametapir (Xeglyze)
  - Approved for age 6 months and older
  - Single application
  - 10 minutes



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### Duchenne muscular dystrophy

- Golodirsen (Vyondys 53) injection
  - Treats patients with Duchenne muscular dystrophy (DMD) who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping
- Viltolarsen (Viltepso)
  - For patients with DMD with confirmed mutation of the DMD gene that is amenable to exon 53 skipping
- Casimersen (Amondys 45) injection
  - For patients with DMD with confirmed mutation of the DMD gene that is amenable to exon 45 skipping
- Accelerated approval



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### New approvals for JIA in Pediatrics

- adalimumab-fkjp (Hulio); RA and juvenile idiopathic arthritis age 4 and older
- tofacitinib (Xeljanz) for polyarticular juvenile idiopathic arthritis in the first 6 months of the disease
- glomumab (Simponi Aria) for polyarticular juvenile idiopathic arthritis in the first 6 months of the disease



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### New approvals in Pediatrics

- dupilumab (Dupixent) for atopic dermatitis approved to age 6 years and older
- mesalamine (Lialda) tablets for ulcerative colitis in pediatric patients who weight at least 24 kg
- ixekizumab (Taltz) for plaque psoriasis in age six years or older



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### New Dosage Forms

- fenfluramine (Fintepla) oral solution for pediatric patients with Dravet syndrome
- dolutegravir (Tivicay PD) oral suspension for pediatric patients age 4 weeks and older with HIV
- solifenacin succinate (VESIcare LS) oral suspension for children age 2 years or older for bladder dysfunction related to neurologic impairment
- Amphetamine (Evekeo ODT) for children age 3 yrs and older with ADHD



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### Expanded indication or age range

- Cannabidiol (Epidiolex) oral solution expanded to include children age 1 year or older with seizures associated with tuberous sclerosis complex
- duloxetine (Cymbalta) approved for pts age 13 to 17 with fibromyalgia
- Spinosad (Natroba topical) lowered age to 4 yrs and older



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### Hepatitis C

- 2.4 million with Hep C in US
- Genotypes 1a, 1b, 2, and 3 most common in US
- Children/adolescents get infected by:
  - Maternal transmission at birth
  - IV drug use



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### Hepatitis C Treatment: Expanded Age Range in Pediatric Patients

- glecaprevir and pibrentasvir (**Mavyret**) for chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection
  - Expanded the indication to children 3 years and older or weighing at least 45 kilograms (kg); previously approved in adults
- Sofosbuvir (**Solvadi**) for chronic hepatitis C genotype 1 or 4 infection
  - Expanded age range to patients age 3 to 11 years
- ledipasvir and sofosbuvir (**Harvoni**) for chronic hepatitis C genotype 1, 4, 5 or 6 infection
  - Expanded age range to patients age 3 to 11 years; and at least 17 kg
- Sofosbuvir and velpatasvir (**Epclusa**) for chronic hepatitis C genotypes 1, 2, 3, 4, 5 & 6
  - Expands age range to age 3 yrs or older, weighing at least 37 lbs



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### 2020 Label Change

- ADHD medications
  - National Pregnancy Registry of ADHD Medications added to label
  - <https://womensmentalhealth.org/adhd-medications/>
  - clonidine (Kapvay)
  - atomoxetine (Strattera)
  - dexamethylphenidate (Focalin)
  - Mydayis (amphetamine/dextroamphetamine)



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### New 2021 Immunization Recommendations

- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine (Twinrix)
  - 3-dose series (0, 1, and 6 months) or
  - 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months)
- HPV updated to clarify that series does not need to be restarted

Wodi et al, 2021



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### Preexposure prophylaxis (PrEP) for HIV – adolescents

- PrEP reduces risk of getting HIV from sex by 99%
- PrEP approved for adolescents in 2018 (Descovy, Truvada)
- PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use.
- For receptive vaginal sex and injection drug use, PrEP reaches maximum protection at about 21 days of daily use.



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## Prescribing PrEP for Adolescents

- Considerations when prescribing for adolescents
  - PrEP is safe in adolescents
  - Screen for barriers related to medication and care costs
  - Medication adherence is required
  - Monthly clinic visits initially, then quarterly
  - Continue to screen for barriers to help them persist with treatment
- Who should be offered PrEP?
  - Sexually active gay and bisexual men without HIV
  - Sexually active heterosexual men and women without HIV
  - Sexually active transgender persons without HIV
  - Persons without HIV who inject drugs
- Follow state laws about consent in adolescents

Tanner et al, 2020, *Learn About PrEP | Preventing New HIV Infections | Clinicians | HIV | CDC*



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## Prescribing PrEP for Adolescents

- Baseline assessment before prescribing PrEP
  - HIV testing
  - Renal function
  - Hepatitis B serology
- Approved medications (weight > 35 kg)
- emtricitabine and tenofovir disoproxil fumarate (Truvada)
  - One tablet (200 mg/300 mg) once daily with or without food
- emtricitabine and tenofovir alafenamide (Descovy)
  - One tablet (200 mg/ 25 mg) daily with or without food
- ADRs
  - GI: nausea, abdominal pain, diarrhea
  - HA



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## Monitoring PrEP for Adolescents

Time Interval	Services at Each Visit
At 3 months after PrEP initiation:	<ul style="list-style-type: none"> <li>• Test for HIV.</li> <li>• Measure serum Cr and CrCl.</li> <li>• Provide medication adherence and behavioral risk reduction support.</li> <li>• Additionally, for                             <ul style="list-style-type: none"> <li>• MSM: screen for bacterial STIs*;</li> <li>• Women with reproductive potential: test for pregnancy; and</li> <li>• PWID: assess access to sterile needles/syringes and to drug treatment services.</li> </ul> </li> </ul>
Every 3 months after the first 3-month follow-up	<ul style="list-style-type: none"> <li>• Test for HIV.</li> <li>• Provide medication adherence and behavioral risk reduction support.</li> <li>• Additionally, for                             <ul style="list-style-type: none"> <li>• MSM: screen for bacterial STIs*;</li> <li>• Women with reproductive potential: test for pregnancy; and</li> <li>• PWID: assess access to sterile needles/syringes and to substance use disorder treatment services.</li> </ul> </li> </ul>
Every 6 months after the first 3-month follow-up:	<ul style="list-style-type: none"> <li>• Measure serum creatinine and estimate creatinine clearance.</li> <li>• For all sexually active patients: Screen for bacterial STIs*.</li> </ul>

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## COVID Vaccine pediatric trials

- Pediatric COVID vaccine trials in process
  - Pfizer in 6 months to 11 years of age
  - Johnson & Johnson in 12 to 18 yr olds, then birth to 18 years
  - Moderna 6 months to 11 years



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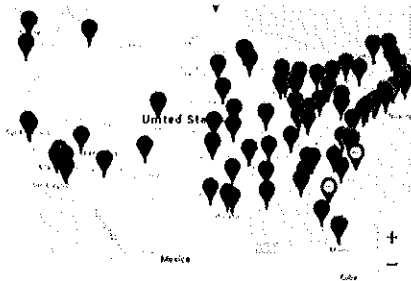
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## Pediatric Trials Network



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## Pediatric Trials Network

- POP02 Enrolling participants
  - Pharmacokinetics, Pharmacodynamics, and Safety Profile of Understudied Drugs Administered to Children Per Standard of Care (POPS)
  - 60 sites, > 400 participants, 70% URM
    - Including children with Down's Syndrome
  - List of drugs that will be studied are: Anakinra, Aspirin, Azithromycin, Colchicine, Canakinumab, Interferon alpha & beta, Lopinavir/Ritonavir, Remdesivir, Ribavirin, Ruxolitinib, Sarilumab, and Tocilizumab

[Pediatrictrials.org](http://Pediatrictrials.org)



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### INCLUDE Study for children with Down's

- (1) Characterize the pharmacokinetics (PK), pharmacodynamics (PD), and pharmacogenomics (PGx) of understudied off-patent drugs administered to children and young adults with DS.
- (2) Develop a stand-alone protocol specifically for those with DS after convening thought leaders and experts.
- (3) Develop a training program for clinical researchers to provide insight and guidance in trial design, recruitment, and engagement issues specifically in this population

Pediatrictrials.org



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### Pediatric Trials ongoing

- Study of ketamine and hydromorphone PK in 2 to 17 yr olds
- Anti-epileptic drugs in obese children age 2 to 18 yrs
  - levetiracetam, valproic acid, topiramate, and oxcarbazepine in obese children
- Long-term Antipsychotic Pediatric Safety Trial (LAPS)
  - risperidone or aripiprazole, in children aged 3-17 years
- Pharmacokinetics and Safety of Commonly Used Drugs In Lactating Women and Breastfed Infants (CUDDLE)
  - Drugs to be studied: Azithromycin, Clindamycin, Escitalopram, Labetalol, Metformin, Nifedipine, Ondansetron, Oxycodone, Sertraline, Tranexamic Acid, Ciprofloxacin, Doxycycline, Levofloxacin, Methylphenidate, Sumatriptan

Pediatrictrials.org



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### Drug Safety/MedWatch Alerts

- [www.fda.gov/safety/MedWatch](http://www.fda.gov/safety/MedWatch)
- Receive updates
  - Sign up for email alerts
- Voluntary adverse event reporting
- Report concerns online
  - Dietary supplements and tobacco also



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**Singulair (montelukast) and All Montelukast Generics:  
Strengthened Boxed Warning - Due to Restricting Use for Allergic  
Rhinitis (3/4/20)**

- **Health Professionals** should:
  - Ask patients about any **history of psychiatric illness** prior to initiating treatment.
  - Consider the **risks and benefits** of montelukast when deciding to prescribe or continue patients on the medicine.
- **Advise all patients of the risk of neuropsychiatric events** when prescribing montelukast. Warnings about these side effects are included in the existing prescribing information; however, many health care professionals and patients/caregivers are not aware of this risk, and suicides and other adverse events continue to be reported.
- Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.
- **Monitor all patients treated with montelukast for neuropsychiatric symptoms.** Events have occurred in patients with and without pre-existing psychiatric disease.

<https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-to-restricting-use>

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**FDA recommends HCP discuss naloxone with all patients when prescribing opioids**

- 7/23/20
- New prescribing information added to all opioid pain relievers regarding discussing naloxone prescription when prescribing opioid pain relievers

FDA, 2020

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**Propylhexedrine misuse**

- 3/25/21
- Propylhexedrine (Benedrex) abuse can lead to dysrhythmias, hypertension and paranoia
- Synthetic stimulant similar to methamphetamine

FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm. | FDA

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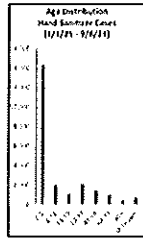
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## Emerging hazards

- American Association of Poison Control Centers
- Hand sanitizer (40% to 90% alcohol)
  - 22,967 exposures as of 9/6/21
- Disinfectants
  - 17,094 as of 9/6/21
  - > 5000 were children < 5 yrs



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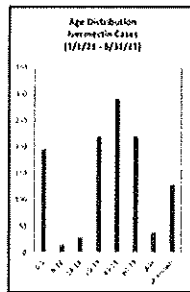
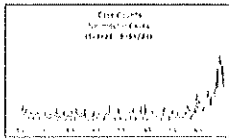
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## Ivermectin

- 1,143 cases in 2021 as of 8/31/21



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## Emerging hazards

- E-cigarettes and liquid nicotine
  - 3829 in 2020, 3453 in 2021 as of 8/31/21
  - The local Poison Center should be contacted if any child is exposed to nicotine products
- Laundry detergent packets
  - 10,572 cases in 2020; 1569 by 2/28/21

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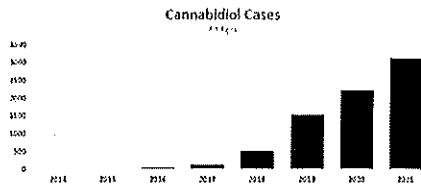
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## Emerging hazards

- Cannabidiol (CBD)
  - 3125 cases by 8/31/21



American Association of Poison Control Centers, 2021

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