Hello, Friends of CUPA,

We present here our third annual report, detailing our activities in preapproval access and beyond. In 2018, we circulated our second Fact Sheet and Recommendations to Congress, and members of the House of Representatives discussed many of our proposals during the floor debate on the federal right to try bill. We were glad to see our policy recommendations adopted, including streamlining IRB review for single patient expanded access and examining barriers to clinical trial participation. CUPA members participated in numerous media appearances and conferences, maintaining the Working Group’s reputation as the go-to source for research, scholarship, and resources on preapproval access. We are proud to share these achievements, and many more, with you. (CUPA members’ names are in bold.)

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If you would like to receive our free monthly newsletter on CUPA’s work and all things related to preapproval access, please contact Kelly McBride Folkers.

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**Preapproval Access via Clinical Trials**

CUPA maintains that the best way for patients to access investigational medical products is through clinical trials. It is not only the easiest path for the largest number of people to receive experimental products, but participants’ health is consistently monitored by researchers and the data collected can be of great value to other participants, the research enterprise, and the general public. Since we began issuing recommendations, we have called upon policymakers to utilize legislative and other means to promote awareness of, access to, and equity in clinical trials.

From our 2017 efforts came a bill authored by Senators Orrin Hatch (former R-UT), Michael Bennet (D-CO), Richard Burr (R-NC), and Robert Casey (D-PA), which was then incorporated into the [FDA Reauthorization Act of 2017](https://www.fda.gov/AboutFDA/BudgetFunding/Reauthorization/ (FDARA). It required:

- the secretary of Health and Human Services, through the FDA Commissioner and in coordination with the NIH director and in consultation with specified stakeholders (e.g., patients, health care providers) to convene a public meeting to discuss clinical trial inclusion and exclusion criteria; issue guidance on clinical trial eligibility criteria;
issue a publicly available report on the topics discussed at the meeting; through the FDA commissioner, issue or revise guidance or regulations to streamline institutional review board (IRB) review for individual patient expanded access protocols, and update any relevant forms; and

- the Government Accountability Office to report to Congress on individual access to investigational drugs through the FDA’s expanded access program.

Accordingly, in April 2018, the Duke-Margolis Center for Health Policy hosted a free public event called “Evaluating Inclusion and Exclusion Criteria in Clinical Trials” at the National Press Club in Washington, DC, available here. Pat Furlong participated in this meeting, on a panel devoted to Utilizing Data from Expanded Access.

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**Ethics & Real World Evidence (ERWE)**

CUPA has become increasingly interested in role that real world evidence (RWE) plays in preapproval access. In July we announced a new project, called ERWE: Ethics & Real World Evidence, which will explore all aspects of RWE — roughly defined as data from sources other than randomized clinical trials — from what qualifies as RWE, to ethical concerns with using it to support providing preapproval access to investigational products, to recommendations for best practices and areas requiring further research, all with the welfare of patients front and center. You may have noticed that several months ago we added a section devoted to RWE articles to our monthly CUPA updates. We are not alone in our interest in the topic. Many companies are beginning to look into whether and how RWE can be used to support drug development, and in December the FDA released the “Framework for FDA’s Real World Evidence Program,” a 40-page document illustrating how the agency will consider RWE, as mandated by the 21st Century Cures Act.

In October, the NYU School of Medicine Division of Medical Ethics partnered with the New York Academy of Sciences to present a conference titled “Healthcare in the Era of Big Data: Opportunities and Challenges.” The event, sponsored by Johnson & Johnson, was organized in part by CUPA co-chair Arthur Caplan, and CUPA members Pat Furlong, Jennifer Miller, and several Friends of CUPA participated in the panel discussions, which explored the integration of data from sources like wearable devices, at-home genetic tests, insurance databases, web searches, among others. At multiple points throughout the two-day symposium, speakers discussed RWE gathered through sources outside of randomized clinical trials and its place in expanded access.

In November, CUPA co-chair Alison Bateman-House and Kay Holcombe participated in a daylong meeting, hosted by the Reagan-Udall Foundation for the FDA, on “Leveraging Real-World Treatment Experience from Expanded Access Protocols.”

###
Institutional Review Boards and Expanded Access
The 2017 FDA Reauthorization Act (FDARA) required the FDA to issue guidance for streamlining IRB review for single patient expanded access, a point that derived from CUPA’s 2017 recommendations. The agency released that updated guidance in October of that year. This year, CUPA continued to study the effect that IRB policies, and variations among them, may have on access to investigational products. Our chief effort was a survey — by Carolyn Chapman, Kelly McBride Folkers, Barbara Redman, Arthur Caplan, Alison Bateman-House, and Jenni Shearston — of U.S. IRB professionals to learn about their experiences with and perspectives on single patient expanded access requests. Results will be published in AJOB Empirical Bioethics. Also, Kelly McBride Folkers and Alison Bateman-House examined publicly available IRB policies in their May 2018 article, “Improving Expanded Access in the United States: The Role of the Institutional Review Board”; they found that consistency is lacking across institutions and suggested this would be desirable. Kelly McBride Folkers was interviewed by Gary Evans about the study in his July 1 article, “Right to Try Law Raises Questions About FDA, IRB Oversight,” for Relias Media. Richard Klein and Clinical Research Pathways’ Marjorie Speers’s disagreed with Folkers and Bateman-House’s conclusions in “Value of IRB in Expanded Access.” Both articles appeared in Therapeutic Innovation & Regulatory Science.

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Educational Efforts
CUPA still sees a pervasive lack of understanding, in all stakeholders, about how to utilize the FDA Expanded Access Program. Thus, we have been deeply invested in efforts to educate anyone interested in preapproval access about what it is and how it works, in addition to how it might be improved. The CUPA website continues to serve as a trustworthy clearinghouse for preapproval access–related information. In December, we updated our Frequently Asked Questions (FAQ) page, which covers all facets of preapproval access. This information is written for a lay audience and is freely available for distribution, though we do ask users to credit CUPA. Our website also features a wide variety of publications and helpful resources for patients, physicians, and industry.

Other educational efforts last year included:

- The NYU School of Medicine Division of Medical Ethics, in collaboration with Janssen Pharmaceuticals, hosted its third Pre-Approval Access Patient Advocacy webinar. It featured Rebecca J. Williams, of ClinicalTrials.gov, and June Wasser, of the Reagan-Udall Foundation for the FDA, who explained how their respective websites can facilitate access to investigation medicines. The recording of the webinar is available here.

- The Division of Medical Ethics and Johnson & Johnson also co-hosted the Global Summit on Pre-Approval Access in Brussels on Nov. 7. Alison Bateman-House spoke, as did several Friends of CUPA.
CUPA members participated in education webinars or talks for a variety of audiences, including:

- U.S. House of Representatives health legislative aides
- Amyloidosis Research Consortium
- Rare Disease Advocates
- Northeast ALS Consortium (recording is available here)
- WCG Foundation
- PRIM&R
- Fight Colorectal Cancer
- Breast Cancer Action
- NYU Langone Health’s Perlmutter Cancer Center
- University of Cincinnati’s Center for Clinical & Translational Science
- Lenox Hill Hospital’s Department of Medicine
- Temple University School of Medicine’s Grand Rounds
- Rutgers New Jersey Medical School’s residency conference
- Tulane University School of Medicine’s Program in Medical Ethics and Human Values
- Kyoto University School of Medicine (Japan)
- University of Southern California’s Flexibility Coalition
- 1st Annual Advanced Research Ethics One-Day Academy, NYU Division of Medical Ethics

If you’d like to have a CUPA member participate in an educational outreach activity for your organization, please email Lisa Kearns.

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Inaugural Visiting Scholar

In early 2018, Carole-Anne Baud, a graduate student and member of the law faculty at the University of Geneva, Switzerland, became the NYU School of Medicine Division of Medical Ethics’s first visiting scholar. She joined us to learn more about preapproval access in the U.S. as part of her work on her doctoral dissertation, which compares U.S. policies with European Union and Swiss laws governing compassionate use. Her time with us also helped her win a four-year grant from the Swiss National Science Foundation to study the regulation of narcotic medicines. In a recent email, she called her time with CUPA “essential” to crafting portions of her dissertation, which will be published in book form by the end of 2019. You can find more about the NYU Visiting Scholar Program here.

###

Federal Right to Try Act

A good amount of CUPA’s efforts in the first half of 2018 was devoted to the run-up to the May signing of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017. CUPA considers all right to try (RTT) laws to be patient-hostile attempts to reduce FDA involvement in the allocation of experimental drugs and has long argued that the
FDA’s expanded access (EA) pathway provides necessary, crucial patient safeguards and has been successful in the decades since it was created.

CUPA members were in demand as the debate over RTT was waged and after the bill’s passage by Congress and enactment into law. Here are some of the many steps we took to oppose the legislation:

- A group of concerned academics — Holly Fernandez Lynch, Gregg Gonsalves, Steven Joffe, Ameet Sarpatwari, Patricia Zettler, and Alison Bateman-House — composed and circulated a letter opposing a federal RTT law. It was delivered to the U.S. House of Representatives’ Energy and Commerce Committee in February and to Senate leadership in April. More than 300 people signed it, and the effort received considerable news coverage, including Rachel Roubein’s “Hundreds Sign On to Letter Opposing ‘Right to Try’ Drug Bill,” in the Hill; Jaime de Leon’s “Academics’ Open Letter Opposes Right-to-Try Bill,” in BioCentury; and Ike Swetlitz’s “Physicians, Ethicists Urge Congress Not to Pass ‘Right-to-Try’ Legislation,” in STAT. In March, another open letter written by this group of academics, which received 187 signatures, was sent to House Speaker Paul Ryan and Minority Leader Nancy Pelosi.

- CUPA released a Fact Sheet and Recommendations for improving patient access to investigational drugs (updated from its 2017 version), which offered suggestions for making the existing FDA expanded access process more appealing to patients, doctors, and industry and which debunked some myths. CUPA sent our fact sheet to House of Representatives staffers, and ranking member of the Energy & Commerce Committee Frank Pallone (D-NJ-6) echoed many of our arguments on the House floor during debate. Our fact sheet was referenced in Carlos Ballesteros’s Newsweek article, “Critics Warn Trump’s Koch-Backed ‘Right to Try’ Bill Is Dangerous for Patients.”

- When an initial House vote did not advance the RTT legislation and it was clear supporters of the bill planned to hold another vote on it, CUPA issued a statement that evaluated a series of false claims that had been made about RTT and expanded access. We released a second statement on March 22 that further reiterated the group’s opposition to any RTT legislation.

- STAT reported that during the RTT signing ceremony, the president predicted that “hundreds of thousands of lives will be saved.” (That figure was upped to 1 million in a White House fact sheet.) That day, Linda Qiu, a fact-check reporter for the New York Times, questioned the claim in “Trump Oversells New ‘Right to Try’ Law,” quoting Alison Bateman-House, who called the figure “extremely unlikely,” and linking to Bateman-House and Lisa Kearns’s research on unethical provisions in state RTT laws. The following day Bateman-House discussed the bill on CBS This Morning, while Arthur Caplan expressed concerns about the financial liabilities patients might face under the new law for Quartz.

- CUPA issued a statement on the new federal RTT law on June 25. We noted that there is much uncertainty about it, including who will be responsible for writing rules and guidance for implementing its provisions and which agency, or agencies, will ensure compliance with them. The Treatment Action Group referred its followers to the
statement, as well as to Alison Bateman-House’s presentation from a February Breast Cancer Action webinar and the CUPA website’s Resources.

- On Aug. 10, Thaddeus Pope aired several concerns about the federal RTT law, and offered suggestions on how oncologists can respond to patients’ questions about it, in “Why Oncologists Should Decline to Participate in the Right to Try Act.” Pope referenced the CUPA website as well as work by Arthur Caplan, Alison Bateman-House, Lisa Kearns, Kelly McBride Folkers, Jennifer Miller, Laura Kimberly, Barbara Redman, and several Friends of CUPA.

- The National Journal’s Oct. 20 article “Right to Try Gets Spotlight in Indiana” described how Indiana Senator Joe Donnelly was campaigning on the success of the federal RTT law and cited Alison Bateman-House’s concerns that the law was not helping patients get access to investigational drugs.

- Health Affairs Blog published an analysis of the implications of the federal right to try law by Alison Bateman-House on Oct. 25 and 26. “‘Right to Try’ Is Law, Now What?: Part 1” compares the new law to the FDA expanded access pathway and asks how the FDA might engage with right to try. Part 2 points to areas that require further study in coming months and years. Ed Miseta’s Nov. 29 article in Clinical Leader, “Now That Right to Try Is Law, What Does It Mean to You?,” reviewed the two pieces.

CUPA is following developments following the enactment of the federal Right to Try Act. We maintain our stance that RTT likely won’t help many patients obtain access to investigational drugs and that EA is a far preferable way to access investigational products outside of clinical trials. If you know of a company that has made medical products available via RTT after the federal law went into effect, please let us know. We are aware of only one claimed case, the collaboration between ERC-USA and UC Irvine announced on Jan. 8. Likewise, if you are aware of any pharmaceutical/biotech companies or medical institutions that have developed policies around RTT, please let us know.

In memoriam: CUPA member Jane Reese-Coulbourne passed away on April 23, 2018. A fierce advocate for patients and a brilliant addition to our team, Jane worked to empower patients and keep them at the forefront of cancer research — before patient-centered drug development was a mainstream idea. You can read more about her life and legacy here. We miss her greatly.

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CompAC
The NYU School of Medicine Division of Medical Ethics has a project with Johnson & Johnson focused on improving non-trial access to investigational medicines. The Compassionate Use Advisory Committees (CompAC) are panels of physicians, bioethicists, and patient representatives who provide guidance to Janssen, Johnson & Johnson’s pharmaceutical
division, on the fair, transparent allocation of its drugs in development. Janssen sought to collaborate with NYU in 2014 to enhance its decision-making support through the utilization of bioethical input for requests of one then-investigational agent. Since then Janssen has expanded the scope of CompAC in collaboration with NYU to address requests for investigational medicines in its portfolio. Although CompAC was co-developed by Arthur Caplan, and several CUPA members participate as chairs, co-chairs, or committee members, CompAC is a separate entity from CUPA. More information about CompAC and publications from the project are on the Division of Medical Ethics website. Also, there is a concise infographic on single patient expanded access. This valuable resource was created by Janssen in collaboration with patient groups.

**GE2P2 Foundation**

Another offshoot of CUPA is the GE2P2 Global Foundation. David Curry is the president of the organization, which works to ensure access to and the ethical allocation of essential medicines and vaccines. While GE2P2 is a separate entity from CUPA, several CUPA members are on its board and/or serve on its Independent Bioethics Advisory Committee (IBAC), which provides advisory support to biopharma organizations and NGOs on expanded access programs, clinical trials, and in other areas.

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CUPA is 100% funded by donations! If you wish to support our research and educational outreach, you can help us with a donation of any amount. Contact Lisa Kearns for more information about how to support our work.

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**2018 Publications**

This year, CUPA members published a wide variety of peer-reviewed publications, op-eds, and commentary pieces. In addition to the articles mentioned throughout this report, here is more of our work (CUPA members’ names are bolded):

- **Kelly McBride Folkers** and **Christopher Robertson** explained the hollowness of RTT legislation in general and highlighted patient-hostile provisions of the federal bill in particular in “**Right to Try’ Does Not Help Patients**,” in Harvard Law’s “Bill of Health” blog on Jan. 19.

- **Alison Bateman-House** and **Christopher Robertson** reviewed the pitfalls of the RTT approach and provided suggestions for improving the FDA’s Expanded Access pathway in “**Right to Try Act of 2017 — A Wrong Turn for Access to Investigational Drugs and the Path Forward**,” in the Jan. 22 issue of JAMA Internal Medicine. Michael Hiltzik continued the conversation — and cited their piece — in “**Right-to-Try Laws Are Hazardous to Your Health — and Now They’re Backed by the Koch Brothers**,” in the L.A. Times. Alicia Ault referenced Bateman-House and Robertson’s article in “**Medical Community Has Sparse Reaction to State of the Union**,” for Medscape on Jan. 31.

• **Lisa Kearns** discussed the “Ethical Implications of Right to Try Legislation” in the New York State Bar Association Health Law Journal’s spring 2018 edition.

• **Andrew McFadyen** and the Isaac Foundation’s Alexandra Hall explained “Why Lawmakers Must Vote Down Right to Try” in the Health Care Blog on March 12.

• **Arthur Caplan, Andrew McFadyen, and Kenneth Moch** called H.R.5247 “fraught with errors” and “poorly written” in “After Right to Try Fails, Here’s How We Can Actually Bring Potentially Life-Saving Drugs to Patients in Need,” in the Health Care Blog on March 19. MedPage Today cited the article in “Making a Better ‘Right to Try’” later that day.

• **Kelly McBride Folkers, Alison Bateman-House, and Arthur Caplan** published an op-ed in Slate on March 21, “‘Right to Try is Merely ‘Thoughts and Prayers’ for the Terminally Ill.”


• Jeremy Puthumana, **Jennifer Miller**, Jeanie Kim, and Joseph Ross published “Availability of Investigational Medicines Through the US Food and Drug Administration’s Expanded Access and Compassionate Use Programs” in JAMA Network Open on June 15. The results of their study show that expanded access programs have provided patients access to investigational medicines when safety and effectiveness was established. The authors conclude that the balance between investigational new drug access and protection of patients from therapies without established safety may be disrupted by the Right to Try Act of 2017.


• Because unapproved treatments often aren’t covered by insurance, some turn to crowdfunding to pay for their treatments. **Kelly McBride Folkers** and **Arthur Caplan**, along with Ford Vox and Angela Turi, published a research letter in JAMA, “Medical Crowdfunding for Scientifically Unsupported or Potentially Dangerous Treatments.” They found that more than $6.7 million had been raised in a 24-month period on online crowdfunding platforms to support a set of treatments that lack evidence to support their use.

**CUPA in the Media**

CUPA is the independent, international expert on preapproval access. In 2018, members’ input and insights were requested for network TV, podcasts, radio, and print media. For example:

• **Alison Bateman-House** commented on the “substantial quirks” of state RTT laws and potential areas of confusion in Conor Hale’s “NEJM: Right-to-Try Laws Could Still Undercut FDA Authority, Even if Ineffective,” in Center Watch Weekly on Jan. 22.
• **Kelly McBride Folkers** added an important correction about RTT and the FDA Reauthorization Act in the comments section of Robert Truog’s “The ‘Right to Try’ Experimental Treatments,” on Health Affairs Blog on Jan. 24.


• **CNBC** featured commentary by **Arthur Caplan**, on Jan. 31, in which he responded to President Trump’s mention of a federal right to try law in the State of the Union address.

• **Richard Klein**’s detailed letter to the editor, “Right to Try Legislation Should Focus on Patients, Not Politics,” in the February issue of P&T Community, offers several rebuttals and clarifications to a December 2017 RTT article by Stephen Barlas.

• **Alison Bateman-House** appeared on NPR’s On Point on Feb. 1.

• **Christopher Robertson** and **Alison Bateman-House** weighed in on RTT for Faye Flam in “Right to Try’ Law Won’t Lead to Miracle Cures,” in Bloomberg View on Feb. 2.

• Sarah Karlin-Smith provided a detailed review of the pros and cons of RTT — and quoted **Richard Klein** — in “Trump’s Controversial New Health Care Idea,” for Politico on Feb. 2.

• **Alison Bateman-House** was cited in Ed Silverman’s “A Compromise ‘Right-to-Try’ Bill Proceeds with Help from FDA, But Could Be a Hard Sell,” in STAT on Feb. 5.

• **Lisa Kearns** was interviewed about S. 204 on SiriusXM’s Doctor Radio on Feb. 8.

• **Alison Bateman-House** is quoted in “The ‘Right-to-Try’ Unproven Pharmaceuticals Is a Right-Wing Scheme,” in the Nation on Feb. 12. The article also mentions one of the open letters CUPA sent to Congress.

• David Kroll recounts his mother’s decades-long battle with cancer, and cites **Alison Bateman-House**, in “My Mom Just Died from Cancer. Here’s Why We Didn’t Seek #RightToTry,” in Forbes on Feb. 28.


• Zachary Brennan quoted **Alison Bateman-House** in “House to Vote Tuesday on ‘Right to Try’ Bill,” on RAPS.org on March 12.

• **Alison Bateman-House** was quoted in the March 12 edition of Politico’s Prescription Pulse newsletter, written by Sarah Karlin-Smith, on the House version of the RTT bill.

• **Alison Bateman-House** was quoted in Dylan Scott’s “Right-to-Try,” the Controversial Plan to Help the Terminally Ill that Just Failed in the House, Explained,” in Vox on March 13.

• **Alison Bateman-House** and others, including some Friends of CUPA, talked about the failed first attempt at passing H.R,5247 on NPR’s 1A radio show, on March 14.

• **Andrew McFadyen** and **Christopher Robertson** discussed the federal RTT bill H.R. 5247 with Sarah Karlin-Smith in “House Passes Right-to-Try on Second Try,” on March 21.

• **Christopher Robertson** talked about H.R.5247 in “Local Medical Experts React to ‘Right to Try’ Bill,” a news report from Tucson’s ABC affiliate, KGUN, on March 22.
Matthew Bin Han Ong did a deep dive into RTT in “Right to Try Edges Closer to Becoming Federal Law: Libertarians Rejoice, But Can it Solve Compassionate Use Problems?,” in the March 23 Cancer Letter. It includes a lengthy interview with Arthur Caplan.

Arthur Caplan told the New York Times’s Katie Thomas that federal RTT legislation would do “somewhere between nothing and absolutely nothing” to help patients in “Why Can’t Dying Patients Get the Drugs They Want?,” on March 23.

Arthur Caplan is quoted extensively in Becky Upham’s “House Okays Right-to-Try Bill on Experimental Drugs,” for Everyday Health on March 26.

Alison Bateman-House’s congressional testimony on RTT is cited in the Defense Research Institute’s “Right to Try Legislation: Worthwhile or Window Dressing?,” published on April 13.

Alison Bateman-House called right to try laws at the state level “constitutionally questionable” in “Can Congress Get ‘Right to Try’ Right?,” on May 3 in Managed Care.

Christopher Robertson weighed in on the promotion of drugs for unapproved uses in Kerry Dooley Young’s article “New Efforts Taking Root to Ease Off-Label Drug Promotion,” on May 15.

Alison Bateman-House is quoted in Erin Durkin’s “Right-to-Try Leaves Pharma Hurdles Unresolved,” for the National Journal on May 23.

Alison Bateman-House commented on the House of Representatives’ passage of RTT legislation on NPR’s Marketplace on May 23.

Alison Bateman-House says that companies have little incentive to honor RTT requests in Alaric DeArment’s “Right-to-Try Bill Passes in House, Heads to President’s Desk for Signature,” in MedCity News on May 23.

Arthur Caplan reminded readers that manufacturers, not the FDA, control access to their products in “House to Vote on ‘Right-to-Try’ Bill for Terminally Ill People,” on CNN.com on May 29.

Henry I. Miller of Stanford’s Hoover Institute invoked Arthur Caplan’s comment about RTT actually being a RTB (right to beg) in a letter to the Wall Street Journal titled “The ‘Right to Try’ Bill Wasn’t Worth Passing,” on June 4.

Alison Bateman-House and debated a RTT proponent on how patients will fare under the new RTT law on NPR’s AirTalk with Larry Mantle, on NPR L.A. affiliate KPCC 89.3 on June 5.

Arthur Caplan discussed how companies tend to prefer the shield of FDA oversight to RTT in Sumathi Reddy’s June 6 Wall Street Journal article about a family’s quest for compassionate use access to a drug for their child, “The ‘Right to Try’ Law Says Yes, the Drug Company Says No.”

Alison Bateman-House says that the FDA is not an obstacle to preapproval access in Marci A. Landsmann’s “Will Right to Try Increase Access to Experimental Treatments?,” in Cancer Today Magazine on June 15.

Arthur Caplan opined on the headache for regulators and patients that charging for drugs under RTT could cause in Michelle Cortez’s “The ‘Right to Try’ Could Cost Dying Patients a Fortune,” on Bloomberg.com on June 20.
• **Tom Watson** and several Friends of CUPA compared and contrasted the new RTT law with the FDA’s Expanded Access Program in “How Will the Federal Right to Try Law Impact Drug Development?,” a guest roundtable for the June 27 Clinical Leader.

• **Richard Klein** and **Alison Bateman-House** are quoted extensively in Carrie Tatro’s detailed FDA v. RTT explainer for How Stuff Works, “FDA’s Expanded Access Pre-dates Right to Try by Decades,” on June 29.

• The Urology Times cited **Lisa Kearns** and **Alison Bateman-House**’s article “Who Stands to Benefit? Right to Try Law Provisions and Implications” in its July 17 article “Right to Try Legislation: Questions Surround its Substance.”

• **Richard Klein** and **Alison Bateman-House** are quoted in Carrie Tatro’s July 18 article for How Stuff Works, “How Right to Try Bypasses the FDA.”

• Claudia Wallis spoke to **Kenneth Moch** and **Alison Bateman-House** for “The So-Called Right to Try Law Gives Patients False Hope,” in the September issue of Scientific American.

• **Alison Bateman-House** discussed “Will Right to Try Help Fewer People Die?” on Larry Rifkin’s American Trends podcast on Sept. 4.

• In an Oct. 2 segment titled “Right-to-Try Law Gives Terminally Ill Access to Experimental Drugs,” for Fox 8 News, Sabrina Wilson talked to **Arthur Caplan** about Louisiana’s right to try law.

• **Lisa Kearns** and **Arthur Caplan** wrote a detailed comment in response to Joe Olechno’s Oct. 9 STAT opinion piece, “Drug Sensitivity and Resistance Testing Could Make ‘Right to Try’ a Real Thing.”

• **Pat Furlong** emphasized the power of disease groups to effect changes in drug development, and **Arthur Caplan** noted the extremely minuscule chances of right to try laws helping patients, in the Oct. 10 installment of “Darwin’s Orphan: A Childhood with Epidermolysis Bullosa,” Eli Cahan’s three-part exploration of “what it really means to have an ‘orphan disease,’” for The Mighty.

• In Lori Robertson and Robert Farley’s FactCheck.org article for Oct. 26, “Trump Stump Speeches: Health Care,” **Alison Bateman-House** took issue with President Trump’s claim that “we’ve had some incredible results already” with right to try.

**CUPA Members at the Mic**

Each year, CUPA members participate in academic conferences, hospital grand rounds, government meetings, patient advocacy and educational webinars, and industry meetings. Here are some highlights from 2018:

• **Christopher Robertson** and **Alison Bateman-House** spoke at Johns Hopkins Carey Business School’s Drug Accessibility and Pricing Symposium on March 19 in Baltimore.

• **Richard Klein**, **Tom Watson**, and several Friends of CUPA spoke at Expanded Access Programs 2018, March 28-29, in Alexandria, VA.

• **Pat Furlong**, **Andrew McFadyen**, **Alison Bateman-House**, and many Friends of CUPA attended and spoke at the World Orphan Drug Conference USA 2018 on April 25-27, in Oxon Hill, MD.
• **Arthur Caplan** discussed “Aspects of the Right to Try Proposed Legislation” at the 2018 Accelerating Anticancer Agent Development and Validation (AAADV) Workshop in Bethesda, MD, on May 2.

• **Alison Bateman-House** discussed “Should Patients Have the Right to Try?” at the Chief Medical Officer Summit, in early May in Boston.

• **Tom Watson, Richard Klein, Alison Bateman-House**, and many Friends of CUPA participated in the Managed Access Programmes and Accelerated Pathways conference in Amsterdam, May 16-17.

• At the BIO International Convention in Boston in early June, **Kenneth Moch, Christopher Robertson**, and several Friends of CUPA discussed the ethics of expanded access and RTT, and **Tom Watson, Alison Bateman-House**, and **Kay Holcombe** examined the differences between expanded access and RTT.

• **Richard Klein** talked about the new federal RTT law and expanded access at the 7th Annual Patient Advocacy Engagement Conference in Baltimore in mid-July.

• **Alison Bateman-House** discussed “Right to Try and Experimental Drugs: What Every Health Professional Needs to Know” at the Food and Nutrition Conference and Expo on Oct. 21, in Washington, DC.

• **Carolyn Chapman** discussed “Reviewing Compassion: IRB Professionals’ Perspectives on IRB Review of Single Patient Expanded Access Requests for Investigation Drugs” and **Kelly McBride Folkers** explored “Establishing a Duty to Increase Racial, Gender, and Socioeconomic Diversity in Medical Research” at the 2018 American Society for Bioethics and the Humanities annual meeting in Anaheim, CA, in mid-October.

• **Kenneth Moch, Tom Watson**, and several Friends of CUPA spoke at Early and Managed Access Programmes Europe, Oct. 23-24, in London.

• **Richard Klein** spoke at the Food and Drug Law Institute’s conference on “Patient Organizations: An Introduction to Drug Law and Regulation,” in Washington, DC in early November.

• **Alison Bateman-House** spoke about preapproval access at IBCD 2018: Innovation in Biomarkers in Cancer Drug Development, in Brussels, in late November.

###

We can’t thank you enough for your continued interest in and overwhelmingly positive support of CUPA. If you would like to receive our free monthly newsletter about our work, contact **Kelly McBride Folkers**. We believe that our research and scholarship into the ethical issues surrounding preapproval access is of vital, practical import to patients and the public. We’re excited to dive into the new year and do even more.

Alison S. Bateman-House (chair)
Arthur L. Caplan (chair)
Jinsy A. Andrews
Nancy Beck
Hayley M. Belli
Carolyn Riley Chapman
David R. Curry
Nancy Dubler
Kelly McBride Folkers
Pat Furlong
Claudia Hirawat
Kay Holcombe
Lisa Kearns
Laura Kimberly
Richard Klein
Andrew McFadyen
Lindsay McNair
Jennifer Miller
Kenneth I. Moch
Robert Nelson
Barbara Redman
Christopher T. Robertson
David Scheer
Lesha D. Shah
J. Russell Teagarden
Tom Watson