EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
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Hearing on the President's Commission on Combating Drug Addiction and the Opioid Crisis

Committee on Oversight and Government Reform
United States House of Representatives

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Johns Hopkins Hospital
Baltimore, Maryland

Written Statement of:
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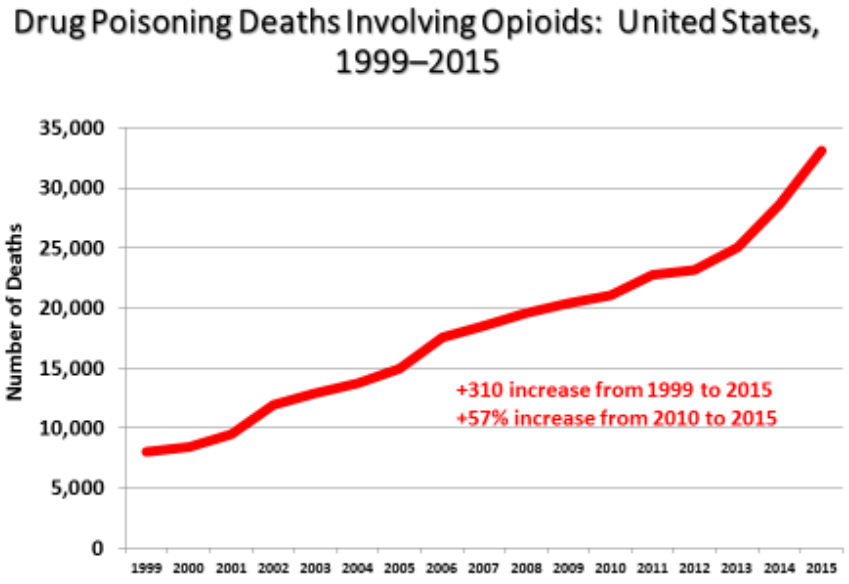
Chairman Gowdy, Ranking Member Cummings, and Members of the Committee, I am pleased to appear before you today to discuss the President's Commission on Combating Drug Addiction and the Opioid Crisis. As a long-term civil servant with over 20 years' experience at ONDCP addressing our Nation's drug abuse problem, it is a tremendous honor for me to serve as Acting Director of the agency. The strong support of President Trump, Vice President Pence, and the Members of the President's Cabinet for our vital work addressing the opioid crisis is deeply appreciated by the dedicated expert staff at ONDCP. This testimony discusses the support provided to the Commission by ONDCP, the Administration's preliminary response to the Commission's recommendations, and ongoing efforts to address the crisis.

Background: Opioid-Involved Deaths

Opioids are a class of drugs that include heroin, which has no recognized medical use and is an illicit drug, and numerous pain medications available via prescription, including morphine, codeine, and semi-synthetic medications such as oxycodone and hydrocodone. In addition to pain relief, opioids can produce a strong sense of euphoria that can lead to chronic misuse and addiction.

The Government has maintained data on deaths involving opioids since 1999. Between 1999 and 2015, the most recent year for which we have final estimates, over 300,000 people have died from drug overdoses involving opioids. Throughout this period such deaths increased each year, rising from 8,050 in 1999 to 33,091 in 2015 (See Figure), to the point that in 2015 an average of 91 people per day died from a drug overdose involving an opioid. Preliminary data from 2016 suggests this rise continues. Perhaps more troubling is the sharp increase in the number of deaths involving synthetic opioids other than methadone, a category that is dominated by illicit fentanyl—since 2013, such deaths have more than tripled, from 3,105 in 2013 to 9,580 in 2015.

Figure



Note: Not all drug poisoning deaths specify the drug(s) involved. Any opioid includes either opioid analgesics or heroin and opium associated with drug poisoning as the underlying cause of death (ICD-10 codes T40.0-T40.4 and T40.6).

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2015* on CDC WONDER Online Database, released 2016. Data were extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on Dec 8, 2016.

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The President's Opioid Commission

In response to these troubling trends and other indicators of the extent and scope of the opioid crisis, on March 29, 2017, the President issued an Executive Order establishing The President's Commission on Combating Drug Addiction and the Opioid Crisis. The Commission was tasked with the accomplishing the following projects:

(a) Identify and describe existing Federal funding used to combat drug addiction and the opioid crisis;

(b) Assess the availability and accessibility of drug addiction treatment services and overdose reversal throughout the country and identify areas that are underserved;

(c) Identify and report on best practices for addiction prevention, including healthcare provider education and evaluation of prescription practices, and the use and effectiveness of State prescription drug monitoring programs;

(d) Review the literature evaluating the effectiveness of educational messages for youth and adults with respect to prescription and illicit opioids;

(e) Identify and evaluate existing Federal programs to prevent and treat drug addiction for their scope and effectiveness, and make recommendations for improving these programs; and

(f) Make recommendations to the President for improving the Federal response to drug addiction and the opioid crisis.

The Commission's charter charged ONDCP with providing an Executive Director and Designated Federal Officer for the Commission. As the Executive Director for the Commission, I was responsible for assigning and supervising ONDCP staff to conduct work for the Commission. As of the beginning of this month, 68 ONDCP staff, detailees, contractors and interns worked over 5,500 hours (nearly 3 full time staff equivalents) conducting tasks for the Commission, including providing research and fact checking in support of the development of the Interim and Final Report recommendations, legal guidance, and logistical and information technology support for Commission meetings and travel. ONDCP's Deputy General Counsel served as the Designated Federal Officer and was responsible for approving or calling all of the Commission's meetings, preparing all meeting agendas, and attending all meetings. It was a pleasure and an honor to work with Governor Christie and the other Commission members. I am proud of the high-quality and professional work that my staff did to support the Commission while continuing to perform their regular duties. The Administration appreciates the dedication and hard work of the Commission members in producing their reports. We are committed to working with Congress; state, local and tribal governments; and non-governmental organizations to combat this crisis.

The Commission was required to submit an Interim and Final Report to the President with their recommendations for combating drug addiction and the opioid crisis. The Interim Report was

submitted to the President on July 31, 2017. The central recommendation called for the Administration to declare the opioid crisis a public health emergency. The President directed the declaration of a national public health emergency on October 26.

The Commission submitted its Final Report on November 1, 2017. It provides a detailed discussion of the history of the opioid crisis and its current status. The heart of the Report is its 56 recommendations for addressing the crisis, which are grouped into the following four categories:

- Federal Funding and Programs;
- Opioid Addiction Prevention, which includes the following three subsections:
  - Prescribing guidelines, regulation, and education;
  - Prescription drug monitoring program enhancements;
  - Supply reduction and enforcement strategies;
- Opioid Addiction Treatment, Overdose Reversal and Recovery; and
- Research and Development.

The Administration is currently reviewing the Commission's recommendations in detail, but our preliminary assessment suggests that we are in broad agreement with much of what the recommendations seek to attain.

Preliminary Assessment of Commission Recommendations

In reviewing the Commission's recommendations there are several that stand out as having especially great potential for impacting the crisis in the near term. The following nine goals are the Administration's summary of the themes of several of the recommendations and a brief discussion of steps that can be taken to achieve each of them.

- *Break down silos and bureaucratic barriers to distributing funding quickly and efficiently to states and those who are on the front lines of fighting this epidemic to deploy evidence-based programs that will save lives*. The Government distributes funding, including funding for drug control programs, via block grants and discretionary grants. The former provide states and localities with maximum flexibility in the use of the funds, which lets them target the problems and populations they deem as top priorities. Funds are distributed based on a formula driven largely by population size. Discretionary grants are competitive and can more accurately target specific problems and populations based upon need. The Government can improve coordination among various agencies providing drug control funding so that they can more accurately target need.

- *Collaborate with states, private sector partners, and other stakeholders to enhance awareness and screening efforts to prevent inappropriate use of opioids and other drugs*. All Federal agencies directly providing addiction treatment use quality metrics to routinely identify and correct program deficiencies (including screening programs), while some fund measure development and collaborate with external stakeholders to assure their validity and meaningfulness to clinical care and good outcomes.

- *Enhance education and training for medical professionals to reduce inappropriate prescribing*. The Government can initiate several steps to achieve this goal, including finalizing the national curriculum on immediate release and extended release/long acting opioids discussed in the Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy and consider other ways to enhance education on opioid prescribing and addiction for prescribers, pharmacists, and emergency medical services workers.

- *Maximize the use of Prescription Drug Monitoring Programs (PDMPs) through better data integration and utilization*. PDMPs have great potential to aid in reducing the misuse and diversion of pain medications. The Government can maximize their use by continued support for federal programs like the Harold Rogers PDMP Grant Program and consider ways to increase PDMP participation by prescribers and pharmacists, and improve data integration and sharing.

- *Strengthen law enforcement efforts to target and take down individuals and organizations that produce and sell counterfeit or illicit drugs*. To achieve this goal the Government can take steps to integrate public safety and public health efforts, enhance intelligence sharing among law enforcement agencies, and revise regulations addressing the distribution of pill presses.

- *Enhance efforts to detect and intercept illicit drugs coming across our borders*. The Government is working to develop enhanced detection capabilities, especially for synthetic opioids such as fentanyl and its analogues, to include technology and canine teams. The United States has made progress in working with China, the primary source country for illicitly manufactured fentanyl and other synthetic opioids; we expect this cooperation will increase. We also are working with Mexico, the source country for the majority of heroin consumed in the United States, on issues including eradication, interdiction, and intelligence sharing.

- *Expand access to evidence-based treatment and recovery services by revising payment policies for federal payers and ensuring private payers are complying with the law*. This year, the Centers for Medicare & Medicaid Services (CMS) solicited "Requests for Information" through Medicare payment rules and the Centers for Medicare & Medicaid Innovation to welcome continued feedback from stakeholders on flexibilities and efficiencies that could improve the availability of high-value and efficiently-provided care for beneficiaries. In response to these Requests for Information, commenters made many suggestions, and those comments are under review. The Department of Labor is committed to vigorously enforcing the Mental Health Parity and Addiction Equity Act. The Commission has recommended that the Department of Labor be given additional enforcement authority, including authority to assess civil monetary penalties to deter bad actors from violating the law, authority to enforce directly against health insurance issuers to obtain widespread correction on their noncompliant policies sold to numerous employers, and additional funding to reach a larger universe of group health plans for enforcement and compliance assistance. ONDCP supports these recommendations.

- *Expand access to overdose-reversing drugs and support services, including housing and employment services by identifying and disseminating best practices for evidence-based programs*. States can enact laws permitting standing orders issued by a prescriber or public health authority that allow naloxone to be dispensed to parties they have not examined, providing they meet certain conditions. State laws can also provide liability protections to health professionals who prescribe naloxone and/or to lay persons who administer it. The Government supports programs that encourage entry into treatment and provision of needed support services.

- *Improve coordination among research funding agencies to identify gaps and expand research related to finding more alternatives to opioids and treatment for addiction, and getting these to patients faster*. The Government can consider developing a national research action plan to survey, assess, plan, and coordinate efforts on research for alternatives to opioids and treatment for addiction. It could conduct a review of regulatory and payer issues concurrently and include payers and regulators in the review process. The Government also can consider funding a public-private partnership to invest in addiction and pain treatments that reduce our reliance on the riskiest opioids.

ONDCP Efforts

While the Commission has recommended a comprehensive set of recommendations to address the opioid crisis, the Administration has continued to implement a wide range of activities to achieve the same goal. For instance, ONDCP is currently undertaking efforts to reduce the opioid problem through its High Intensity Drug Trafficking Areas program and the National Heroin Coordination Group to address the opioid crisis through coordination of law enforcement and public health initiatives and enhanced coordination of intelligence, and public health and safety efforts among Federal, state, local and tribal partners.

High Intensity Drug Trafficking Areas Heroin Response Strategy

ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program is a locally-based program that responds to the drug trafficking issues facing specific areas of the country. Law enforcement agencies at all levels of government share information and implement coordinated enforcement activities; enhance intelligence sharing among Federal, state, local, and tribal law enforcement agencies; provide reliable intelligence to law enforcement agencies to develop effective enforcement strategies and operations; and support coordinated law enforcement strategies to maximize available resources and reduce the supply of illegal drugs.

Currently, there are 28 regional HIDTAs covering 49 states, Puerto Rico, the U.S. Virgin Islands, and Washington, D.C. Regional HIDTAs facilitate cooperation among law enforcement to share intelligence and implement coordinated enforcement activities and support law enforcement strategies that leverage available resources to reduce the supply of illegal drugs in the United States. The HIDTA program includes more than 6,000 Federal agents and analysts and more than 15,000 state, local, and tribal officers and analysts. HIDTA initiatives (task forces) and investigative support centers in each of the regional HIDTA programs disrupt and dismantle organizations that transport and distribute heroin, illicit fentanyl, and other opioids that are either illicitly produced or diverted from legal distribution channels. In addition, the regional HIDTA

programs have a number of initiatives as described below that specifically target heroin and other opioids.

In October 2017, I committed $4.8 million in HIDTA funds to support the Heroin Response Strategy (HRS) to address the heroin and opioid epidemic by coordinating the efforts of 10 regional HIDTA programs across 22 states and the District of Columbia.[1] The HRS was first launched in 2015 with an initial investment of $2.5 million to fund operations in 17 states. In 2016, the initiative received an additional $3.9 million in HIDTA funds and was expanded to three more states. At present, the HRS brings together the following regional HIDTA programs: Appalachia, Atlanta/Carolinas, Chicago, Indiana, Michigan, New England, New York/New Jersey, Ohio, Philadelphia/Camden, and Washington/Baltimore. Earlier this month, I spoke at the HRS annual symposium and witnessed firsthand the innovation and sense of urgency this initiative has brought to our broader effort to curtail the opioid epidemic.

The HRS has an ambitious goal: to leverage its strategic partnerships to target the organizations and individuals trafficking deadly drugs like heroin and illicit fentanyl so that overdoses are reduced and lives are saved. The HRS is achieving this goal by creating a human network spanning the law enforcement and public health communities to share actionable information. For example, drug intelligence officers track and relay drug-related felony arrests of out-of-state residents and then report this information to the individual's home law enforcement agency. Since January 2016, drug intelligence officers have shared more than 22,000 of these felony arrest notifications. In multiple instances, the sharing of drug intelligence across the HRS network has resulted in the identification and arrest of heroin/fentanyl distributors linked to outbreaks of fatal and non-fatal overdoses.

Shortly, the HRS will support the implementation of pilot projects that will identify opioid overdose "hot spots" to serve as testing grounds for targeted efforts. In partnership with the Centers for Disease Control and Prevention (CDC), the HRS will launch interventions designed to address the specific needs of the communities they are situated in and will evaluate these efforts to determine their efficacy and the feasibility of implementing them in other communities facing similar overdose challenges. The participating regional HIDTA programs will monitor the progress of the pilot projects as well as the HRS overall. As in 2016, the HRS participants will prepare a report outlining the initiative's achievements.

National Heroin Coordination Group

ONDCP, in coordination with the National Security Council staff, established the National Heroin Coordination Group (NHCG) in October 2015. The NHCG serves as the hub of a network of interagency partners and coordinates Federal Government activities to address the heroin problem and reduce the availability of heroin, illicit fentanyl, and fentanyl analogues in the United States. The NHCG's first task was to write, staff, and oversee the implementation of a Heroin Availability Reduction Plan (HARP), a five-year plan to synchronize existing efforts and strengthen the partnerships already in place to address this problem, focused on a clearly

[1] The HIDTA Heroin Response Strategy covers the following states: Connecticut, Delaware, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia.

defined result: *a significant reduction in the number of heroin-involved deaths in the United States due to a disruption in the heroin and fentanyl supply chains, a detectable decrease in the availability of those drugs in the U.S. market, and the complementary effects of international engagement, law enforcement, and public health efforts.*

The NHCG continues to implement the HARP. Eight times each month the NHCG leads forums for sharing information, lessons learned, and identifying gaps and redundancies among Federal Government partners, state, local, and tribal partners, and the Intelligence Community. A monthly Public Health Webinar provides public health professionals from across the country a forum to share information on the opioid crisis from the state perspective. A monthly Federal Law Enforcement Secure Video Teleconference allows Federal law enforcement agencies to discuss case-related data and law enforcement trends in a small, classified environment. A weekly Intelligence Core Group Secure Video Teleconference includes interagency intelligence analysts from across the Intelligence Community and law enforcement officers, and maintains the Intelligence Community's awareness of heroin and fentanyl trafficking patterns around the world.

Integrating these three webinars is a monthly "Big Tent" Webinar that brings together the public health and public safety communities to share information on trends, new developments, lessons learned, and best practices in addressing the opioid crisis nationwide. Additionally, the NHCG conducts a monthly video teleconference with interagency partners and elements of the U.S. Embassy staff in Mexico City who are involved in heroin and fentanyl coordination efforts with their Government of Mexico counterparts. In all cases, these forums allow participants to share the most current information on the opioid crisis, from actions taken to interrupt the supply chain to addressing effective public health initiatives, and allows ONDCP to quickly identify gaps and redundancies that can be addressed to more effectively align efforts and resources.

Other Federal Efforts

The Administration hit the ground running with respect to the opioid crisis. Within his first 100 days, President Trump engaged in critical ways on the opioid issue. He signed an Executive Order directing the creation of the Commission. He convened a roundtable with stakeholders, which included affected individuals and families and showcased to the American public that people can and do recover. Then, based on the Commission interim report's recommendations, he directed the declaration of a national public health emergency, which offers new options and opportunities for HHS to coordinate response. In conjunction with this effort, HHS's Office of Civil Rights issued important guidance on how medical professionals can communicate with patient family members to help them get their loved ones the addiction treatment help they need. In September, First Lady Melania Trump held a listening session with families and spoke publically about her intent to shine a spotlight on this issue moving forward. Afterward, the President gave a major speech highlighting how addiction has affected him personally and the ways he intends to address the crisis.

I have never seen the Federal staff so mobilized to address drug related issues as I have seen under President Trump, and we are starting to see real progress. Highlights include:

- The National Institutes of Health has taken the first steps of a public-private partnership with industry to expand addiction treatment and pain research.

- Federal law enforcement have announced a number of major activities against both prescription opioid and illicit traffickers, including regional and national multi-agency strategic initiatives; targeted intelligence sharing and data exploitation of heroin and opioid overdoses and deaths; increased deployment of tactical diversion squads; increased engagement between criminal health care fraud investigators and prosecutors and those with expertise in drug and violent crime investigations and prosecutions; pilot projects addressing the choke points for entry of fentanyls and novel psychoactive substances into the United States; two of the largest dark web takedowns in history; multiple indictments against Chinese illicit fentanyl manufacturers, Mexican and South American cartels, and North American traffickers; and an indictment of a pharmaceutical company CEO under Racketeer Influenced and Corrupt Organizations (RICO) conspiracy charges for bribing doctors and pharmacists to prescribe fentanyl products, as well as actions across the controlled drug supply chain industry, including wholesalers/distributors, pharmacies, and practitioners.

- HHS has published draft revisions of the FDA Blueprint for Prescriber Education, which is part of the Risk Evaluation and Mitigation Strategies now for immediate release and long acting opioids, to make pain treatment safer and has circulated for public comment a new curriculum for provider training for both short- and long-acting opioids. These and other new tools will help train providers and help them use those guidelines.

- CMS issued guidance to state Medicaid Directors to improve access to and quality of opioid treatment and other substance abuse treatment that includes section 1115 waivers to the Institutes for Mental Diseases exclusion as part of comprehensive opioid/substance abuse strategy, so states can offer the entire continuum of care for addiction, including inpatient treatment for substance use disorder in a residential treatment facility. We anticipate this streamlined guidance will encourage states to follow the lead of those who are already using this process to make medication-assisted treatment more available.

- Our colleagues at FDA have intensified their efforts to make prescription opioids safer by recommending removal of the dangerous opioid Opana from the market, and I am pleased to say that the manufacturer quickly complied. FDA also decided to expand the classes of opioids which have additional risk safeguards, including provider and patient information requirements to include the most frequently prescribed opioids, the short-acting ones.

- We continue to work to expand opioid addiction prevention and treatment with new grants to states, which include funding for medication-assisted treatment, $485 million of which went to states this year. We also awarded several grants for drug courts, veterans' courts, and treatment alternatives to incarceration and diversion programs, so we do not lose an important chance to help people get care through the law enforcement and the criminal justice systems.

- And because prevention is vitally important, we are working with colleagues across the Executive Office of the President to formulate a new media campaign based on the scientific evidence concerning what works to change young people's attitudes and beliefs about these drugs.

- At the same time CDC has expanded its efforts to target opioid policies at the state level to all 50 states, including expanding and improving PDMPs and the training of providers.

- This month, a collaboration between colleagues in the Department of Transportation, HHS, and the Department of Defense produced a much-needed revision to EMS Clinic Guidelines and the EMS model scope of practice for all levels of emergency medicine staff. This will provide staff who work on ambulance crews with information about overdose reversal and will ensure states have a model to design their policies, to help ensure that crew members can use naloxone regardless of their level of medical specialization, like law enforcement has been doing for some time now in many parts of the country.

- HHS's Office of Inspector General (OIG) is focusing on preventing opioid misuse in federally-funded health care programs. In July 2017, in collaboration with state and local law enforcement partners, HHS OIG and Department of Justice (DOJ) components conducted the largest health care fraud takedown to date, in which 120 defendants were charged with prescription opioid-related crimes. Also in July 2017, HHS OIG released a report identifying 401 Medicare providers who are most responsible for prescribing questionable amounts of opioids to beneficiaries at serious risk for overdose. These providers are now being further evaluated for possible action by HHS OIG, DOJ, CMS, and other partners with enforcement and administrative authorities to address prescription drug fraud and diversion.

Several Federal agencies worked with the international community to schedule important fentanyl precursors and other synthetic opioids responsible for many overdose deaths, and recently I learned more first-hand about how Customs and Border Protection is training dogs to detect opioids.

Conclusion

The current opioid crisis is the deadliest drug epidemic on record to ever hit the United States. It has devastated families and communities across the Nation, ignoring economic, social, and racial/ethnic distinctions. It affects the Nation's economic productivity, public health and safety, and national security. In response, the President has directed the declaration of a public health emergency coordinating, implementing, and promoting Federal, state, local and tribal public health and safety efforts to: (1) reduce the availability of illicit opioids and diverted opioid pain medications from reaching the U.S. market; (2) disrupt and dismantle drug trafficking organizations; (3) launch evidence-based prevention programs; (4) expand access to opioid overdose reversal medication to save lives; (5) provide access to opioid treatment programs to enable sustained recovery from opioid addiction; and (6) improve coordination among research funding agencies to improve the efficiency of developing and delivering alternative pain medications.

I appreciate the Committee's ongoing interest in working with ONDCP on drug policy matters, and I look forward to having ONDCP continue to work with Members of this Committee on combating the opioid crisis.

Richard J. Baum

Acting Director, Office of National Drug Control Policy (ONDCP)

Richard J. Baum currently serves as the Acting Director of National Drug Control Policy (ONDCP). Mr. Baum has served ONDCP for two decades in a variety of positions through four presidential administrations. His previous role was Director of ONDCP's International Division. During this time he led or co-led the development of numerous strategic documents, including the *National Drug Control Strategy*, the *National Southwest Border Counternarcotics Strategy*, the *Synthetic Drug Action Plan*, and the *Strategy to Combat Transnational Organized Crime*.

Over his years at ONDCP he has worked both national security and domestic drug policy issues, served in the Office of Legislative Affairs, and has been a part of the U.S. delegation to the United Nations' Commission on Narcotic Drugs and other meetings with key international partners. Prior to joining ONDCP's staff in 1997, he was a criminal justice writer and researcher and served for six years as a Republican Congressional Staff Member.

Mr. Baum is also an Adjunct Professor at Georgetown University's McCourt Graduate School of Public Policy where he teaches a course on the history of American drug policy. He resides in Falls Church, Virginia with his wife and two children.