U.S. Department of Health and Human Services

Thomas Jefferson Model United Nations Conference

TechMUN XXVI

High School Specialized Agency

Co-Chair: Ishaan Dey

Co-Chair: Varun Saraswathula

TechMUN | | Thomas Jefferson High School for Science and Technology | | April 20-21, 2018

Letter from the Dias:

Hello Delegates:

We are very pleased to have you attend TechMUN XXVI, and it is our pleasure to introduce the US Department of Health and Human Services. Our main inspiration for this committee was with the current atmosphere in healthcare policy, where crucial changes made by Congress and the bureaucracy fly under the radar, yet impact millions of Americans on the most fundamental level. In the words of President Donald Trump, "Nobody knew healthcare could be so complicated." While we understand that healthcare policy is highly convoluted and difficult to grasp, we hope that this committee provides a realistic forum that emulates the conservative policy objectives being currently pursued in Washington. In fact, delegates in this committee will be part of the same "universe" as the Big Pharma crisis committee, which we hope will provide interesting analysis on the current relationship between the industry and bureaucracy.

As chairs, we will be acting as the head of the department, who is currently Secretary Alex Azar, III. Each delegate present will be representing HHS assistant administrators, executive representatives, and legislative leaders on both the state and federal level. While we have not invited outside analysts, lobbies, or interest groups, we will be interacting with the Big Pharma crisis committee. As a specialized committee, our actions will translate into crisis updates for Big Pharma, but their actions may not directly affect us. You may call pharmaceutical executives to testify before a US Senate Committee Hearing, and we hope that may provide insight towards the actions and potentials avenues towards action in resolving the present issue. The objective, for in this committee, will be crafting bureaucratic action for the HHS that resolves the opioid crisis aids states in creating more efficient healthcare systems by

reforming Medicaid. Some efforts may fall under the purview of the DOJ or other departments, and for that, resolutions will take the form of policy recommendations.

This committee will be set in real time, meaning that the information included in this background guide may change by the time you begin deliberation. Due to the pace at which bureaucratic regulation moves in Washington, it is imperative that you consult healthcare policy outlets and think tanks regularly for updates on both topics. In addition, given the hyper-polarized environment in which healthcare is discussed today, it is important that each one of you evaluate your sources of information. We would personally recommend the Kaiser Family Foundation as the gold standard for nonpartisan, objective analysis of current healthcare issues, but feel free to venture to other left or right-leaning organizations for ideas and information, so long as you acknowledge their implicit bias in the matter. We have attached an appendix with excellent starting points for your use. Remember, there is no substitute for strong research. We have provided a list of additional resources regarding health policy basics (this may be more helpful in understanding Topic 2, as Topic 1 is relatively straightforward).

If you have any questions regarding the committee forum, your position, a policy idea, or the background information, or just want to say hello, feel free to email us at HHSTechMUN2018@gmail.com. Good luck delegates!

Sincerely,

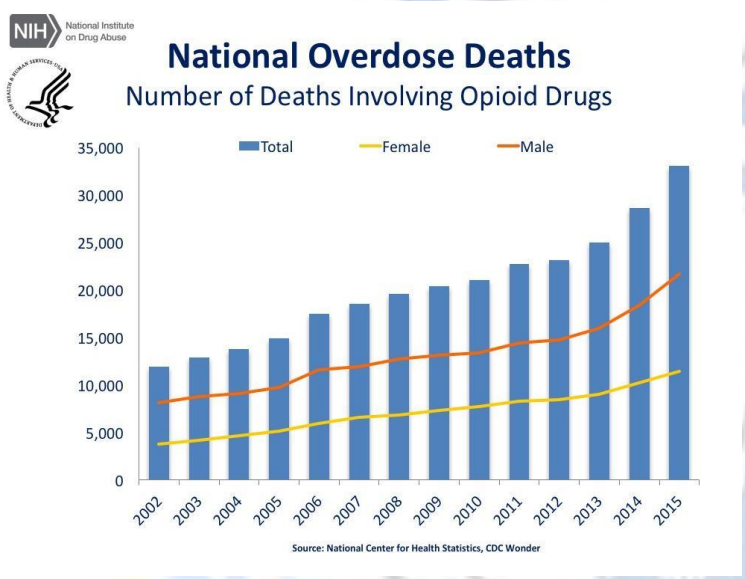
Ishaan Dey & Varun Saraswathula

Chairs, TechMUN XXVI

Topic 1: The Opioid Crisis

Introduction

The "Opioid Epidemic" is the term regarding the misuse and abuse of opioid based drugs (both prescription and illicit) that has pervaded American communities since the late 1990s, but particularly over the past ten years. Abuse opioids contributes to severe addictions, and in many cases, diseases that arise from unsafe methods of using drugs, such as contaminated needles and paraphernalia. Often, opioid addictions end in overdoses, or lethal doses, of drugs.



Opioids are a class of drugs that interact with opioid receptors on nerve cells throughout the body and the brain. Many opioids are legal and prescribed by physicians, including oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, and morphine. These opiods are used in pain management and relief, and when used in controlled amounts, are safe and effective. However, prescription opioids also produce feelings of euphoria, and can be abused by taking larger or unprescribed doses, thus leading to dependence and addiction. While prescription opioids are a major part of the crisis, however, illegal opioids, all of which are "scheduled narcotics," make up a large portion of the opioids consumed in the United States. These illicit opioids, most notably heroin, have contributed to the epidemic increasingly over the past several years (National Institute on Drug Abuse).

Opioid abuse has gripped the nation in a deadly crisis that affects many different demographics in all parts of the nation: urban, suburban, and rural areas. Drug overdoses are now the leading cause of death among Americans under the age of 50, likely attributed to the 406% increase in heroin overdoses between 2006 and 2014 (CBS News). Coupled with increases in sales of prescription drug overdoses, the regularity of drug abuse has led to the opioid crisis being declared a national emergency by President Trump in late 2017.

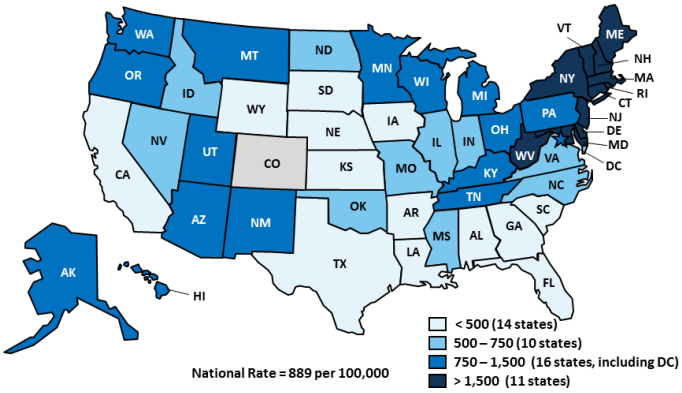
Origins of the Crisis

During the 20th century, medical professionals widely disregarded pain as a key component of patient treatment. In the late 1990s, this changed. Throughout the decade, a growing body of medical literature suggested that clinicians move to begin treating pain, in addition to their physical ailments, to the point where the American Pain Society, formed the prior year, launched a 1996 campaign with the slogan: "Pain. The Fifth Vital Sign." This movement led to significant policy changes in hospitals across the nation. In 1998, the Veterans Health Administration, the largest health system in the country, mandated to its physicians that all doctors ask patients about their current pain, asking them to rank it on a simple Likert scale. If the patient did report some pain, doctors were mandated to, in the words of Sarah Kliff from Vox Media, "do something about it."

Figure 1

Medicaid Enrollees with Opioid Addiction, FY 2013

Prevalence per 100,000 enrollees



Note: Colorado data were unavailable. 2012 data were used in Rhode Island and Kansas, because of lack of data in 2013. Data shown as prevalence per 100,000 enrollees.
Source: KFF estimates based on analysis of data from the FY 2013 Medicaid Statistical Information System (MSIS). Enrollees with opioid addiction were identified using ICD-9-CM codes provided in the claims data.

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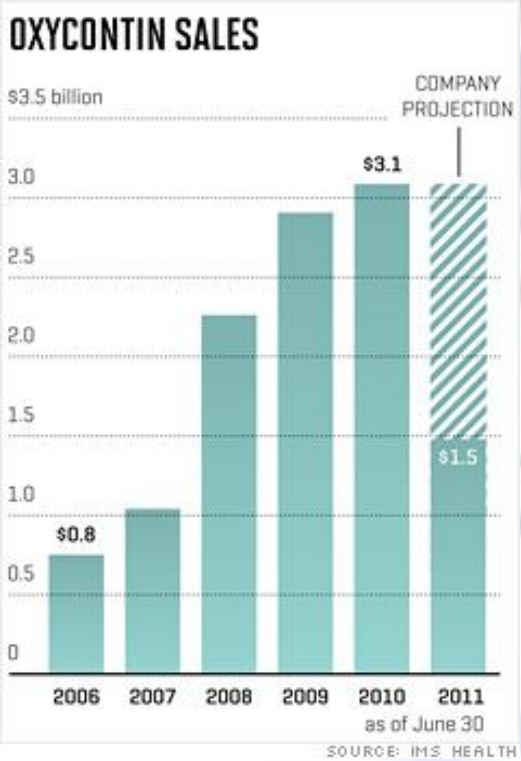
This directly led to the misleading marketing adopted by pharmaceutical companies in the late 1990s. In 1996, OxyContin was developed by Purdue Pharma, and immediately marketed as a long-acting opioid. This differed from previous opioids in that OxyContin did not deliver a large high up-front, instead releasing the active ingredient over a longer period of time. For this reason, Purdue Pharma maintained that OxyContin would be non-addictive, despite providing no empirical evidence that it indeed had lower addiction rates than traditional opioids.



Eventually, more prescriptions were filled for opiods when patients had back pain or recent surgery, instead of end-of-life care and chronic pain was previously the norm. In 1996, OxyContin sales leaped from $44 million, at a little over 300,000 prescriptions, to over $3 billion in 2002, with 14 million prescriptions (Van Zee, 2009). This misleading claim is considered to be the primary reason for the large in opioid prescriptions and subsequent overdose-related deaths, after multiple Senate Committee Hearings investigated pharmaceutical representatives (Newsweek). As found in a 2007 Virginia case, Purdue Pharma and its affiliate business groups were found guilty to criminal charges of misrepresenting the effects of OxyContin.

The mechanism by which they encountered this is of great interest. From 1996 to 2001, Purdue Pharma hosted more than 40 pain management conferences across the nation, hosting over 5000 doctors, most of them primary care physicians. Through this, Purdue was able to showcase the benefits of prescribing the opioid to their patients and drastically alter the

prescribing practice of medical practitioners. Purdue was found to use databases that compiled profiles on physician prescribing patterns; if a certain physician was found to have high number of chronic pain patients, regional sales representatives would be encouraged to target those physicians in an effort to expand a consumer base. This encouragement often took the form of sales bonuses; the average bonus was found to be around $71,000 in 2001 (Van Zee, 2009)

Purdue Pharma was not the sole pharmaceutical company behind such aggressive marketing tactics. In fact, it was the first of many large corporations to take advantage of poor enforcement of existing FDA marketing regulations (which stated that "prescription drug advertising and promotion are truthful, balanced, and accurately communicated") (Van Zee, 2009). Subsys, a fentanyl-based painkiller produced by Insys Therapeutics, was approved by the FDA in 2012 for use as a painkiller for "opioid intolerant" cancer patients, or patients not responding to common drugs such as OxyContin. However, current federal efforts are investigating what is known as "off-label use," or marketing of Subsys to patients without cancer. One major insurer, Anthem, filed a lawsuit in mid-2017, alleging that over half of its patients receiving prescriptions for Subsys did not have cancer, much less have an opioid intolerance.

These actions largely characterize the effort by pharmaceutical companies to mislead patients, medical professionals, and federal agencies, and until recently, there has not been an united, significant effort from the federal government to address the issue.

Current Efforts by the Trump Administration

On October 26, 2017, President Trump, through the HHS, declared the opioid crisis a public health emergency. Despite this statement, he did not allocate additional funds to address the issue, nor did he propose many concrete solutions to solve it. He suggested a program

similar to Nancy Reagan's "Just Say No" campaign, which encouraged kids to simply refuse drugs, but he also agreed to remove a rule which prevents Medicare from funding drug rehabilitation programs. Earlier, however, President Trump signed an executive order establishing a Commission on Combating Drug Addiction and the Opioid Crisis. The commission is primarily geared toward identifying potential federal responses to the crisis and responses from previous administrations (The White House).

Furthermore, the White House FY 2019 requests $5 billion to the HHS over the next five years to combat the opioid epidemic, primarily through overdose reversal programs, treatment, and recovery support services. The budget allocates money for advertising campaigns, increased programs at the state level, first responder programs, and drug surveillance programs to prevent further abuse. The budget calls for the involvement of different parts of the federal government including health-based departments to prevent abuse of drugs and research organizations (like the NIH) to conduct scientific investigations of opioids. The budget also calls for law enforcement agencies (like the DEA) to ensure that drug trafficking programs both domestically and overseas are dismantled, and it requests $2.2 billion in funding.

Questions to Consider:

1. How can the HHS expand access to recovery and rehabilitation programs for substance abuse?
2. What avenues for cooperation between other federal agencies are there? How effective would this be?
3. How can the HHS, using its regulatory power, prevent pharmaceutical companies from employing deceptive tactics to sell their drugs?

Topic 2: Medicaid Reform

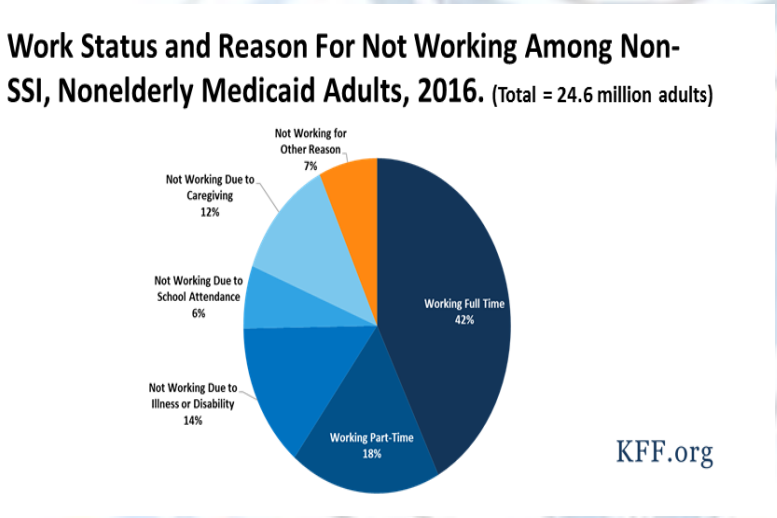
In the United States, Medicaid is a joint federal and state program aimed to help with medical costs for individuals with limited income and resources. In other words, Medicaid is a government insurance program designed to help those who are too poor to afford other means of obtaining health insurance. The distinction between Medicaid and Medicare is notable, Medicare being a government funded program for those aged 65 or older, while Medicaid is for those who qualify as low-income individuals. In fact, Medicaid is the largest such program in the United States, providing free health care coverage to more 74 million people.

Both programs were borne out of the Social Security Act (1965) under former President Lyndon B. Johnson and dedicated as mandatory entitlement spending. However, Medicaid was dramatically expanded in 2013 by the passage of the Patient Protection and Affordable Care Act (ACA), colloquially known as Obamacare. This expansion would have changed eligibility criteria from household size, household income, and other factors, to simply covering all individuals earning less than 138% of the federal poverty line. However, 17 states opted to not expand Medicaid after the Supreme Court of the United States ruled in *National Federation of Independent Business v. Sebelius* that states do not have to agree to the expansion in order to receive previously designated levels of funding from the program.

With the 2016 election of President Donald Trump, however, the White House and Congress have undertaken efforts to dismantle and replace the ACA. In its proposed budget for Fiscal Year 2019, the White House suggested that the ACA shifted too much of Medicaid's responsibility away from the states to the federal government, and proposed to increase the flexibility of states to "modernize" Medicaid eligibility requirements and benefits. In fact, the Trump administration proposed imposing work requirements as an eligibility requirement for

Medicaid, marking an important policy shift from previous administrations, Republican and Democrat (Office of Management and Budget).

Proponents of this system allege that in its current form (without work requirements to get benefits), Medicaid disincentivizes work and forces people to remain in poverty without hopes of getting out. With being within 138% of the poverty line an eligibility requirement, many suggest that Medicaid recipients choose to stay in low-paying jobs in order to continue receiving benefits, citing that only 24% of them work full time, and 44% are unemployed. Proponents of the Trump administration's new policies also claim that Medicaid itself has become a financial burden to states, indicating that with the ACA's increases in Medicaid enrollment after its implementation, Medicaid itself has come to cost more than originally estimated by the Congressional Budget Office (CBO), such as in Kentucky, where the cost of Medicaid expansion was $2 billion over budget. Most importantly, however, they claim that Medicaid is inferior to most other health care options and that many physicians refuse to accept it because of this, making the whole debate moot (The Hill).



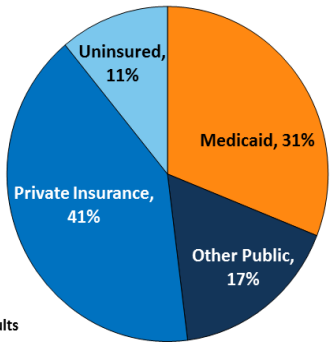
In light of Medicaid's shortcomings, many believe that the Trump administration's plan to introduce work requirements will incentivize those who absolutely need Medicaid to begin working, move away from government dependency, and become more self-sufficient, thus

leaving more money for those who truly depend on it for survival. At the same time, this drop in Medicaid enrollment can save the government over $1 trillion over the next decade.

Others, however, say that the new proposal is counterintuitive, and may not actually help increase employment or improve health. Their major concerns are that the state of Kentucky has only vaguely defined how to verify compliance. Furthemore, opponents of the new requirements say that the idea that working and independence improves health is backwards, and that improved access to health care services is what allows individuals to return to work. The new plans, they suggest, will actually hurt the hundreds of thousands of individuals in Kentucky who have already registered. They also want to make it clear that if these individuals could get jobs, they would not be registered in Medicaid in the first place (The New York Times).

Figure 1

Insurance coverage status of nonelderly adults with disabilities, 2015



Total = 22.1 million nonelderly adults with disabilities

NOTES: Includes adults ages 18-64. Excludes those in long-term care facilities. Disability includes limitation in vision, hearing, mobility, cognitive functioning, self-care, and/or independent living. Other public includes those with Medicare (excludes Part A only), military or Veterans Administration coverage (excludes Tricare), and other government or state-sponsored health plans. Medicaid includes those dually enrolled in Medicare and Medicaid. SOURCE: KFF analysis of 2015 National Health Interview Survey data.

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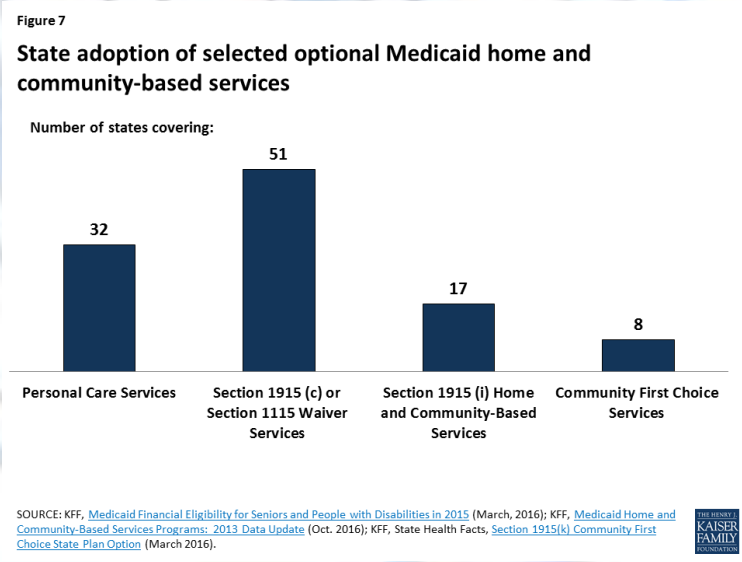
Work requirements, however, are simply one type of "innovation" that states can undertake to improve access to healthcare and affordable pricing. Both the Social Security Act and Affordable Care Act enable states to apply for Medicaid waivers in order to use federal funds in a way not explicitly allowed by federal rules. The intention of these waivers is to improve quality of service or dissemination of benefits throughout statewide communities.

One type of waiver that states employ is section 1115 of the Social Security Act, or "Medicaid Demonstration Waiver." Section 1115 gives the Secretary of Health and Human

Services the ability to allow states to forgo certain Medicaid requirements and/or use federal Medicaid funds in ways that would not otherwise be allowed by federal regulations. Several states have implemented section 1115 waivers primarily to expand Medicaid coverage and availability. These waivers make changes in eligibility requirements and benefits to Medicaid recipients (Kaiser Family Foundation).

Section 1115 waivers to guide federal funds to populations (particularly vulnerable populations) that are not specifically mentioned in Medicaid policy. For example, states may apply for a section 1115 waiver to redirect federal money to individuals with HIV/AIDS or mental illness because they do not have specifically allocated funds at the federal level. Section 1115 waivers, however, must be "budget neutral" for the federal government, meaning that to the federal government, the cost of that state's program with the waiver cannot exceed that of the state's program without the waiver.



Another waiver that states often implement is section 1915 of the Social Security Act, which involves Medicaid Home and Community Based Services (HCBS) waiver programs. The HCBS program differs from the rest of Medicaid in that it focuses on medical care that takes place in home and community-based settings rather than in traditional hospital or clinical settings. Section 1915 waivers, based on a 2012 study, mostly focused on developmentally disabled (including autism) populations, the elderly and disabled, medically fragile populations,

and those with brain injuries. These waivers, like Section 1115 waivers, aim to redistribute federal funds to particularly vulnerable populations (Centers for Medicare and Medicaid Services).

The historical use of waivers, such as section 1115 and 1915 waivers, is to expand Medicaid availability and ensure that everyone who needs Medicaid can receive it. The Trump administration, however, is trying to distance itself from this traditional application of waivers and instead use them to ensure that only those who need Medicaid the most can have access to it. Work requirement waivers, like those implemented in Kentucky, provide an insight into the current trajectory of Medicaid reform.

Questions to consider:

1. How can State Innovation Waivers provide relief from unpopular Obamacare policies?
2. To what extent are certain waivers, such as exemptions of the ten essential health benefits legal?
3. How can states maintain support for Medicaid work requirements or provide other forms of care to non-Medicaid eligible populations?

Appendix

Helpful Links

https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf

This is the proposed White House budget for Fiscal Year 2019. It contains the resource allocation for each department of the HHS. The Budget-In-Brief for the entire executive branch has also been published, and while that highlights what actions will be taken by departments such as the Department of Justice and Drug Enforcement Agency, our committee will focus more on actions that the HHS could implement itself.

https://www.kff.org

This is the Kaiser Family Foundation, a renowned nonpartisan think tank dedicated towards objective health policy analysis and coverage. This will provide strong background on issues such as Medicaid reform, where legal definitions or industry terminology may sometimes be confusing.

https://www.nytimes.com/, https://www.washingtonpost.com/, https://www.theatlantic.com/, https://www.politico.com/

These are highly reputable organizations with strong coverage and investigative journalism on a multitude of health topics. Though the op-eds often do have a slight liberal slant, they provide unparalleled depth on specific issues within topics such as drug pricing transparency, for example.

https://www.heritage.org/,

The Heritage Foundation is a large conservative think tank based in Washington, D.C. They provide many policy proposals and analysis from a conservative or libertarian perspective; in fact, the idea for an individual mandate originated from here in the 1980s.

https://khn.org/news/tag/podcast,

The Kaiser Family Foundation's media arm, the Kaiser Health News, provides weekly podcasts that discuss current events (with regards to health policy). The host, Julie Rovner, brings in a panel of journalists that break down convoluted policy initiatives and analyze the effects of legislation. They are an excellent source of non-partisan, comprehensible, and current information. Other notable podcasts include The Impact from Vox Media and Two Docs Talk. These both do not typically look at current events, instead focusing on specific policy topics and doing in-depth analysis on them.

HHSTechMUN2018@gmail.com

That's us! As your chairs, we want you to understand the health policy behind the opioid crisis and Medicaid reform very well. But it's hard, and we definitely are aware of that. Always ask around to people like your parents who may be able to help on definitions with things such as "What's a deductible?" which will save you a lot of time and confusion. Don't hesitate to contact us, and we'll do our best to reply promptly. Again, don't wait until the last minute to prepare. Good luck!

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Committee Dossier

Below is a list of positions in the Health and Human Services meeting. We've done our best to add the wide prespectives of not only HHS Agency leadership, but also Cabinet members, Congressmen and women, and State leaders. Be sure to research not only the two topics, but your position and agency's stance on the issues at hand. The Big Pharma committee is primarily made up of Pharma company and Healthcare executives, along with a few governmental leaders (with no overlap cross-committee).

HHS Agency Directors

1. Seema Verma, Administrator of the Centers for Medicare and Medicaid Services (CMS)
2. Anne Schuchat, Acting Director of the Centers for Disease Control and Prevention (CDC)
3. Elinore F. McCance-Katz, Assistant Secretary for Mental Health and Substance Use (SAMSHA)
4. Scott Gottlieb, Commissioner of Food and Drugs (FDA)
5. Jerome M. Adams, Surgeon General of the United States (USPHS)
6. Gopal Khanna, Director of the Agency for Healthcare Research and Quality (AHRQ)
7. Francis S. Collins, Director of the National Institutes of Health (NIH)
8. Steven Wagner, Acting Assistant Secretary of the Administration for Children & Families (ACF)

Executive Office of POTUS

1. James W. Carroll, Director of National Office of Drug Control Policy (NODCP)
2. Mick Mulvaney, Director of Office of Management and Budget (OMB)
3. Chris Christie, Chair, President's Commission on Combating Drug Addiction and the Opioid Crisis

Cabinet

1. Jeff Sessions, Attorney General of the United States (DOJ)
2. David J. Shulkin, Secretary of Veterans Affairs (VA)

State Leaders

1. Governor John Kasich (R-OH)
2. Governor Jim Justice (R-WV)
3. Governor Charlie Baker (R-MA)
4. Governor Roy Cooper (R-NC)

Senators and Congressmen

1. Senator Mitch McConnell (R-KY)
2. Senator John McCain (R-AZ)
3. Senator Lindsey Graham (R-NC)
4. Senator Susan Collins (R-MA)
5. Senator Orinn Hatch (R-UT)

6. Senator Lamar Alexander (R-TN)
7. Representative Paul Ryan (R-WI)

Position Paper Requirements

Overview

The Position Paper that delegates will be writing is a culmination of the most important pre-conference research that they have done, acting as a summary of research and the representative view of their state on the issues presented to their respective organ. Position Papers are due, in hard-copy format, before the first committee session on Friday. Any delegate without a Position Paper will be deemed ineligible for awards, so remember to bring a copy for collection, and a copy for personal use! Remember to not plagiarize any aspect of the paper - our chairs and directors will be checking every paper for plagiarism and we expect a full MLA works cited for each. Failure to do so might result in delegate or school delegation disqualification!

Basic Structure

- Times New Roman, 12pt font, single spaced
- A cover page with delegate name, nation, council, school
    - Delegates can add additional details, including national flags, seals, or any symbolic edits to Model United Nations, to demonstrate thoughtful presentation and attention to details.
- One page per topic with titled sections: background, country policy and possible solutions

  - Background: This section should include an overview of the topic. What is the current situation, and what are the main nations affected? This should be the shortest section on the paper.
  - Country Policy: What past actions has your country taken to address the issue at hand? What does your nation think about the topic? This section should take up a majority of your paper, as delegates should remain representative of their country's view throughout committee
  - Possible Solutions: This should be the most interesting part of a delegate's position paper. Solutions should incorporate both research and creativity, with a focus on improving past actions conducted by their respective council. Feel free to come up with unique solutions to the dilemmas at hand which you plan to bring up during committee
- Complete MLA bibliography and in-text citations for all statistics and sources used

Helpful Hints

- Remember to avoid first person pronouns! Staying in character is always important at Model United Nations conferences!
- Always use the active voice!
- Avoid fancy language which can distract your chairs from the true meaning of your paper!
- Remember to remain formal when writing your position paper and try to show all the research that you have done for committee, as this is the first impression that your chairs will have of you!