

# Patient Advocacy Engagement Toolkit

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## Advocacy basics

Learn about the basics of advocating for the PI community including what advocacy is, why you should do it, and the many different ways to go about it.

### What is advocacy?

Advocacy is the act of promoting a cause or policy aimed at supporting the needs and interests of an individual or a group of people with common interests. It is often employed to educate a policymaker on a specific topic, such as primary immunodeficiency (PI). By advocating to elected officials and regulators, you can engage in the creation and implementation of laws that are important to the PI community. It is not necessary to be a professional lobbyist to influence how policy and legislation are created. Advocacy often entails building relationships with policymakers and, if successful, will alter existing policy and may inspire the creation of new policies and programs.

### Why advocate?

When people like you get involved in the legislative or regulatory process through advocacy, you not only personalize an issue but also make lawmakers and regulators aware of the unique needs of individuals with PI. Utilizing personal experiences and factual information surrounding a certain issue can help influence key decision-makers and aid them in better serving constituents across the country. IDF can provide guidance, resources, information, and advice for successfully advocating to legislatures and agencies, but really, it all starts with you.

### Grassroots and grasstops advocacy

Grassroots advocacy consists of engaging the general public—more specifically, the PI community—in advocacy at the local, state, or federal level to collectively support or oppose a certain issue. Grasstops advocacy, on the other hand, involves recruiting individuals who have strong influence on or personal connections with the decision-makers or officials involved in a particular issue. While much of the advocacy at IDF and other organizations employ the grassroots approach, including grasstops advocacy in our endeavors is just as essential.

In order to successfully engage in grasstops advocacy, it is crucial for those in the PI community to keep IDF abreast of the relationships they have with officials at all levels of government. These connections —whether personal, political, or business-related—are an important element to achieving IDF’s policy priorities. We encourage all community members to use the relationships tool (“[Identifying existing relationships with elected officials](#)” in Supplemental materials) to make us aware of these key connections. For assistance, view the relationship guide and the training tutorial below. With the help of this resource, IDF can engage in a more targeted approach to advocacy goals in legislatures and beyond.

**Watch:** [IDF Grasstops Advocacy Training Video](#)

### Ways to advocate

Now that you know how vital it is to advocate, it’s time to learn to employ two important advocacy routes: legislative and agency advocacy.

**Legislative advocacy** consists of engaging with legislators on either the state or federal level in an attempt to influence laws and policies. **Agency advocacy** has the goal of altering or creating regulations by influencing regulators and other agency officials. The details of legislative and agency advocacy are explored in the sections on [legislative advocacy](#) and [agency advocacy](#). Although these two types of advocacy may involve engaging with different entities, the methods used to advocate are very similar. The information below details ways that members of the PI community can participate in both legislative and agency advocacy.

**Watch:** [How to Contact Your Legislators](#)

### How to tell your story

The first step in advocacy is for community members learn about the importance of your personal story and how to best share it with decision makers.

**Watch:** [How to Tell Your Story](#)

Additionally, creating your own “Faces of IDF” handout is a great way to tell your story to officials. Watch this [video to learn from IDF Public Policy staff how to create and use this advocacy tool](#).

### Personal visit

A face-to-face meeting with a legislator or agency official is one of the most effective ways to make your voice heard and influence legislation or regulations. Personal visits allow you to educate policymakers firsthand on issues involving PI and recommend actions they should take. Additionally, an in-person meeting provides a clear connection between the issue at hand and real constituents like you.

Reminders for a fruitful personal meeting:

- Prepare your key points beforehand and be ready to discuss them clearly.
- Be on time and dress professionally.
- Keep your discussion brief. You can expect about 15 minutes.
- Follow up with the policymaker after your meeting. Restate your message and thank them for their time.

### Telephone calls

An in-person visit may not always be possible or practical, and in these cases, a telephone call or virtual meeting are other options you can use to effectively advocate for issues important to the PI community. Staff in legislative and agency offices are very diligent about keeping track of calls, as well as the issues the calls were regarding. While chances are you will not have an opportunity to speak directly with the official, engaging in a scheduled phone call or virtual meeting with a staff person means your concerns will still be heard.

Reminders for a productive call or meeting:

- Be brief and concise – aim to take no more than a few minutes with your call/meeting.
- Write out your thoughts in advance to ensure you capture your main talking points.
- Use the "[Sample phone script](#)" in Supplemental materials to get started, but try to put it in your own words so it does not sound like you are reading.

- Thank the individual for their time.

## Letters and emails

Drafting a letter or email is a productive and convenient way to advocate for or against a policy or regulation. Written correspondence can be advantageous since it allows an advocate to craft their message without time restraints and the pressure of a real-time interaction. Letters and emails are most compelling when they are brief, concise, and courteous. In your letter or email, be sure to clearly state the issue at hand, what your position on the issue is, and what action you would like the official to take. While email is commonly used informally in today's world, it is important to remember to maintain formality when interacting with officials in a legislature or agency.

Reminders for crafting a letter/email:

- Be sure to use the proper forms of address when writing to government officials. See "[Addressing an elected official by letter/email](#)" in Supplemental materials.
- State the issue of concern and identify the bill or regulation you are writing about within the first paragraph.
- Describe the issue as you understand it and briefly explain the effect of the aforementioned bill or regulation on this issue.
- Explain how these outcomes would impact you directly or indirectly. This is your opportunity to personalize the issue and tell your story.
- Use the "[Sample email](#)" in Supplemental materials as a guide, but try to put it in your own words.
- Conclude by re-stating what action you would like the official to take and thanking the official for their consideration.

If writing your own letter or email seems daunting, sign up for IDF's [Action Alerts](#). These alerts let you easily sign on to templated letters or emails and send them directly to your federal or state legislators, letting them know how policies affect the PI community. Sign up for Action Alerts to be notified when IDF needs your voice on an issue.

## Testifying at public hearings

During the deliberation of both legislation and regulations, public hearings are a significant part of the process and provide a unique opportunity for advocates to testify. These hearings provide committees and boards with more detailed information about the issue at hand and allow advocates to put a human face on the impact of the officials' considerations.

Brevity, a good understanding of the facts, personal experiences, and courtesy – all elements that are pertinent when speaking with individual officials – are also applicable when testifying in front of a group of officials that form a committee or board. Begin your testimony by clearly stating your position on the issue and why you hold it, as well as what you are asking the officials to do. Most often, testimonies with a combination of personal stories and accurate factual information are powerful and compelling. Addressing the issue from personal experience also provides an opportunity to assess the impact of their actions on real people like yourself.

### Reminders for successful testimonies:

- Prepare your statement before attending the hearing. If possible, bring copies for members of the committee or board.
- Dress professionally, as if you are going to a job interview.
- Aim to speak for 2-3 minutes. This is usually equivalent to about 1.5 pages of typed material.
- Formally greet the officials and introduce yourself before beginning your testimony. Then, clearly state your reason for testifying before them. This is usually to support or oppose a piece of legislation or regulation.
- Following your testimony, ask for questions the officials may have. If you do not know the answer, tell the official that you or IDF will get back to them with a response.
- Thank the committee or board and follow up on the policy or regulation.

**Watch:** [2017 Congressional Testimony on SCID Newborn Screening video](#)

### Using the media and social media

Engaging in advocacy using the media or social media can be an efficient way to reach a high volume of individuals with a similar amount of time and effort. The media and press often help shape public opinion on issues both big and small. Therefore, letters to the editor and op-eds can be very influential advocacy tools, especially since the editorial page is often one of the most widely read sections of a newspaper. Additionally, Facebook posts or tweets can also be powerful tools that help bring widespread attention to a policy or regulation that impacts the PI community.

### Reminders for media outreach:

- Succinct and direct sentences that express the objective of the letter will attract more readers.
- Avoid a negative tone in letters and posts.
- Try having a peer read your message before posting or publishing.
- Reach out to IDF if you would like them to review messaging prior to publishing.
- Catch the readers' attention from the start to keep them reading.

## Legislative advocacy

By providing expertise and resources to policymakers on issues impacting the immunocompromised, rare, and chronic disease community, advocates can help ensure the unique needs of those in the PI community are met by the laws that legislators produce. Learn about legislative advocacy and how to effectively engage with state and federal legislators.

### What is legislative advocacy?

Legislative advocacy consists of engaging with legislators on either the state or federal level in an attempt to influence laws and policies. A policy is a set of ideas or plans or a method of action used to guide and determine decisions. Most legislators know very little about PI-related issues and the impact that they have on the lives of people like you. By providing expertise and resources to policymakers on issues impacting the immunocompromised, rare, and chronic disease community, advocates can help ensure the unique needs of those in the PI community are met by the laws that legislators produce.

Effective legislative advocacy can accomplish the following:

- Build relationships with your legislators.
- Educate and impact policymakers' decisions.
- Alter existing policies.
- Inspire the creation of new policies.

Remember that your legislators work for you! They are elected by the constituents in your district or state and are interested in the issues concerning you and others in your area. While oftentimes elected officials must balance competing interests, they are always looking for ways to better serve their constituents. Your advocacy helps highlight the issues and causes that legislators should focus on and the actions they should take to keep voters happy and healthy. Use "[Identifying and understanding your legislators](#)" in Supplemental materials to identify your legislators and interpret who they represent.

It is important to note that IDF and its advocates engage with legislators in a nonpartisan way. This type of nonpartisan advocacy is often referred to as issue advocacy. Issue advocacy means putting personal ideologies and political party affiliation aside and focusing on specific issues that affect the PI community.

### Federal legislative advocacy

A clear understanding of the legislative process is necessary for effective advocacy. The federal legislature, Congress, consists of two chambers: the House of Representatives ("the House") and the Senate. The House has 435 members – representatives that are elected by individual districts in states across the nation. The Senate has 100 members – two senators from each state. These Senators and Representatives report to Washington, D.C. to represent the interests of you and other constituents in your district/state.

The steps below are a summary of the process that occurs when a bill becomes a federal law, along with suggestions on how advocates like you can get involved every step of the way.

#### Bill drafting

Before a piece of legislation can be introduced, it must be drafted and sponsored by a legislator. Oftentimes, policymakers confer with advocates and other interested parties to help generate ideas and craft language for

a new piece of legislation. Any federal legislator – whether they are a representative or senator – can draft and introduce a bill.

- Get involved: Advocates may contact their federal Senator or Representative (through a phone call or email) to recommend ideas for new legislation or propose language for one currently being drafted. Visiting the district office of a legislator is also an accessible way to get in contact with a lawmaker and their staff. Advocating to legislators about the need for certain legislation is often the first step in the creation of a bill.

### Bill introduction

After a policy is drafted and sponsored by the necessary lawmaker, it is formally introduced to the legislative body and receives a bill number. To stay updated on what legislation is currently in the Senate or House of Representatives, advocates can visit [Congress' website](#) and utilize the legislation search tool.

- Get involved: Once a piece of legislation is introduced, advocates can urge their Senators or Representative to support or cosponsor the bill. Also, if the bill is favorable to the PI community, advocates can express their support and appreciation through contacts with media outlets such as [letters to the editor of the Washington Post](#) or other newspapers, contacting local TV and radio outlets or posting support on social media. Public support from yourself and the media has a large influence on a bill's success.

### Bill referred to committee(s)

Following the introduction of a piece of legislation, it is referred to a committee that deals in matters relevant to the bill's content. Committee members may hold hearings on a bill, propose and adopt amendments, and decide whether to approve the bill or let it "die" through lack of committee action.

- Get involved: Advocates may write to members of a committee and encourage a hearing on bills that are of consequence to the PI community. While most advocates will be unable to testify at hearings at the federal level, constituents can suggest possible questions or comments to a friendly legislator for their use during such hearings. Additionally, if a member of the committee is your representative or senator, you can contact their office to advocate for their support or opposition of the bill in committee.

### Floor action on bill

If a bill is reported favorably by a committee, it will be placed on the Senate or House calendar to be debated by the full chamber. During this debate, lawmakers are able to express their support or opposition of a bill and are able to discuss the details of the bill with their fellow legislators. When the debate closes, the full chamber votes to approve or defeat the legislation.

- Get involved: During this stage of the federal legislative process, advocates have the ability to contact their own legislators to convince them to speak in favor or in opposition to a bill when it is put up for debate. Also, contacting other policymakers that may be key to the passage or defeat of a bill can significantly further the advocate's cause.

### Referral of bill to the other chamber

After a piece of legislation is passed in the House or Senate, it is referred to the other chamber where it will follow the same course through committees and to the floor of the other chamber.

- Get involved: While a bill passes through the opposite chamber, advocates have an opportunity to replicate their efforts in order to get the bill passed in the second chamber. Contacting your legislators, advocating to committee members, and persuading policymakers before a floor vote are all relevant tactics as the bill moves through the final steps.

## Bill packages

At the federal level, many times, bills that are introduced on a narrow topic may be combined with other bills as part of a “bill package” that includes language from a number of bills generally on the same subject, such as healthcare. This larger bill package will have a different bill number than the original bill. Combining a bill into a bill package is often the only opportunity to move a bill out of committee and get a vote in both chambers. The best way to know if a bill has been included in a larger package is to stay engaged with IDF advocacy so that you can be alerted of this.

## Action by the President

When a bill has passed in both the House and Senate, the piece of legislation is then sent to the President. If the President approves the bill, it is signed by them and becomes law. If the President disapproves of the legislation, they may veto the bill. While uncommon, Congress can override a president’s veto and pass a bill over a president’s objections. This override can be accomplished by obtaining the support of two-thirds of the House members and two-thirds of the Senate members. The third path a President may use is taking no action on a bill. If Congress is in session, ten days of inaction from the President means the bill automatically becomes law. If Congress is not in session, inaction from the President means the bill will be “pocket vetoed” which means the bill does not become law and has the effect of being vetoed.

- Get involved: It is difficult to sway the stance of a President and his advisors on an issue, but it still possible to bring attention to the issue the legislation addresses. Utilizing media and social media can be useful for advocates looking to make an issue more widely known and understood. While your efforts may not directly reach the White House, influencing public opinion on these issues through the media is an effective way to influence this part of the process.

## State legislative advocacy

Nearly all state legislatures mirror the federal government in the fact that they are bicameral institutions, often including a House/Assembly and a Senate. The representatives and senators in the state legislature are officials that report to the capital of your state and deal with issues that are relevant in your specific state. These representatives and senators should not be confused with your federal representatives and senators, who were mentioned in the previous section – these are two different groups of officials. Federal legislators in Congress often have more visibility, but advocating in your state legislature is just as important and influential.

**Watch:** [“Advocating for Healthcare Access in the States” video](#)

While each state has distinct rules and procedures that dictate the process, passing a bill in a state legislature is not unlike the process that occurs in Congress. To see details on the specific process in your state, which may vary slightly from the process outlined below, visit [your state legislature’s website](#).

## Bill drafting

Before a piece of legislation can be introduced, it must be drafted and sponsored by a legislator. Oftentimes policymakers confer with advocates and other interested parties to help generate ideas and craft language for [Patient Advocacy Engagement Toolkit, Immune Deficiency Foundation](#)

a new piece of legislation. Any legislator – whether they are a representative or senator – can draft and introduce a bill.

- Get involved: Advocates may visit their legislator’s office at either the state capital or in-district, if they have one, to recommend ideas for new legislation or propose language for one currently being drafted. Arranging an in-person meeting is the most persuasive way to get in contact with a lawmaker and their staff, however contacting a state senator or representative through a phone call or email can be a very effective alternative. Advocating to legislators about the need for certain legislation can often be the first step in the creation of a bill.

### Bill introduction

After a policy is drafted and sponsored by the necessary lawmaker, it is formally introduced to the legislative body and receives a bill number. To stay updated on what legislation is currently in the Senate or House of your state, you can [visit your state legislature’s website](#) and utilize the legislation search tool.

- Get Involved: Once a piece of legislation is introduced, advocates can urge their senators or representatives to cosponsor or speak out against the bill. Also, advocates can express their support or opposition to local and state media through letters, op-eds, and phone calls. Public opinion and the media have a large influence on the actions a legislator will take.

### Bill referred to committee(s)

Following the introduction of a piece of legislation, it is referred to a committee that deals in matters relevant to the bill’s content. Committee members may hold hearings on a bill, propose and adopt amendments, and decide whether to approve the bill or let it “die” by lack of committee action.

- Get involved: Committee hearings at the state level are one of the most effective ways for advocates to engage with the legislature. Preparing a testimony, suggesting possible questions or comments, and contacting committee members directly are all ways in which advocates can influence the success of legislation while it is in committee. Using your personal experiences to show how a bill will affect you is your most powerful tool, and doing so with a committee is a powerful way to use it.

### Floor action on a bill

If a bill is reported favorably by a committee, it will be placed on the Senate or House/Assembly calendar to be debated by the full chamber. During this debate, lawmakers are able to express their support or opposition of a bill and are able to discuss the details of the bill with their fellow legislators. When the debate closes, the full chamber votes to approve or defeat the legislation.

- Get involved: During this stage of the state legislative process, advocates have the ability to contact their own legislators to convince them to speak in favor or in opposition to a bill when it is put up for debate. Also, contacting other policymakers that may be key to the passage or defeat of a bill can significantly further the advocate’s cause.

### Referral of bill to the other chamber

After a piece of legislation is passed in the House/Assembly or Senate, it is referred to the other chamber where it will follow the same course through committees and to the floor of the other chamber.

- Get involved: While a bill passes through the opposite chamber, advocates have an opportunity to replicate their efforts in order to get the bill passed in the second chamber. Contacting your legislators, testifying during the committee hearing, and persuading policymakers before a floor vote are all relevant tactics as the bill moves through the final steps.

### Action by the Governor

When a bill has passed in both the House/Assembly and Senate, the piece of legislation is then sent to the state's governor. If the governor approves the bill, it is signed and becomes law. If the governor disapproves of the legislation, they may veto the bill or send it back to the legislature with changes. Governor vetoes – like presidential ones – can be overridden by the state's legislature. The margin of votes required to override a veto varies from state to state. Lastly, a governor can take no action on a piece of legislation. In some states, a governor's inaction will lead to the bill becoming law after a certain period of time.

- Get involved: If a governor is hesitant about signing or vetoing a bill, media and social media can be useful tools for advocates to bring attention to the issue. When a governor does sign an important piece of legislation, advocates can write supportive letters to the media or attend a signing ceremony to show their support.

Now that you have learned about how to advocate to both the federal and state legislatures, don't forget to [sign up for IDF's Action Alerts](#). This tool is an excellent way to stay updated on the legislative initiatives and advocacy goals of IDF and those in the PI community and to be notified when your voice is needed.

## Agency advocacy

Following the creation of a law, federal and state agencies are responsible for creating the rules and regulations that determine how that law is implemented. Learn about agency advocacy and how to effectively engage with local, state, and federal agency officials.

### What is agency advocacy?

A regulatory or administrative agency is a public authority that is responsible for managing and supervising activity in a specific area of government oversight. When a legislative body creates a law, these policies are often too vague to be implemented successfully—this is where an agency comes in. After its passage in the state or federal legislature, a law is sent to a relevant agency, where details are supplied such as the interpretation of the new law's meaning and how it will be enforced. To do this, agencies create rules and regulations that govern how this law will influence current activity in a specific area. Without the action of agencies, laws would not be nearly as effective. The visual below demonstrates the rulemaking process of a typical agency.



Now that you know what an agency is and what it does, it's important to emphasize why getting involved in the regulatory process is just as crucial as doing so in the legislative process. You have the unique opportunity to educate agency officials about the impact a regulation or rule will have on you and others in the PI community. Whether through a meeting, letter, phone call, or public comment, agency advocacy helps ensure that the laws passed by Congress and state legislatures are implemented the way they were intended. In collaboration with IDF, you can help create a real impact in the rules and regulations created by agencies at both the state and federal levels.

### When and how to engage with agencies

Advocating to agencies is not only just as important as advocating to a legislature, but it can oftentimes be a more direct route to achieving real change. While laws must be passed by a majority of a legislature through a long process, changing a regulation must be approved only by the agency with oversight. Therefore achieving advocacy goals can often be done more readily using the regulatory avenue rather than the legislative one.

The main challenge that discourages most advocates from advocating to agencies is navigating when to advocate, which agency to engage with, and how to effectively do so. IDF is here to help you maneuver these challenges and be successful in your agency advocacy.

Deciding when it is appropriate to advocate to an agency can be simple. When you see a law has passed and is being referred to an agency to develop rules and regulations, ask yourself the following questions:

- Will this new law affect me or others in the PI community?
- Does the enforcement of this law affect my care or the care of others with PI?
- Did I advocate for the support or opposition of this law in the state or federal legislature?

If the answer to any of these questions is yes, you should consider advocating to the agency and educating the officials on the possible effects of their regulations. A general guideline is if the rule or regulation created is of interest to you or the PI community, it is a good opportunity to partner with IDF and advocate to the agency.

The next step to agency advocacy is deciphering which agency is the appropriate recipient of your efforts. The simplest way to narrow down which agency to advocate to is to recognize whether the regulation or rule is a local, statewide, or federal issue. Oftentimes, issues can overlap across local, state, and federal agencies. Collaborating with IDF is an excellent way to distinguish at what level you should engage on an issue.

#### Local issue?

Engage with your city/county Department of Health/Human Services.

Regulations regarding:

- The city/county's public health: Includes the immunization of local residents, the screening and prevention of diseases city/county-wide, and maintaining standards for the environment throughout the city/county.
- The financing and delivery of personal health services: Includes providing medical care to low-income/disabled city/county residents, funding and maintaining public hospitals and treatment centers, and ensuring a proper standard of care.
- The providers of medical care: Includes providing coverage for care and deciding who can provide that care to citizens in the county/city.

#### Statewide issue?

Engage with your State Department of Health/Human Services, State Pharmacy and Therapeutics Committee, or State Health Insurance Commissioner.

Regulations regarding:

- The state's public health: Includes the immunization of state residents, the screening and prevention of diseases statewide, and maintaining standards for the environment throughout the state.
- The financing and delivery of personal health services: Includes providing medical care to low-income/disabled state residents, funding and maintaining public hospitals and treatment centers, and ensuring a proper standard of care.

- The providers of medical care: Includes providing coverage for care and deciding who can provide that care to citizens in the state.

## Federal issue?

Engage with one of the administrations of the Department of Health and Human Services (HHS) including the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the Health Resources & Services Administration (HRSA), and the National Institutes of Health (NIH).

Regulations that involve the health of individuals across America, typically regarding:

- Research: Includes protecting the wellbeing of research participants and ensuring the integrity and credibility of research findings.
- Public health: Includes surveying the nation's health status and health-related needs, providing health assistance and resources to states, and protecting the U.S. against international health threats.
- Drug and device safety: Includes allowing new medical treatments to reach the public quickly while also ensuring that new treatments are both safe and effective.

## Advocating with federal agencies

### Federal advisory committees

One way for advocates to get involved with agencies and the regulations they produce is to become part of or present information to federal advisory committees. Advisory committees are responsible for counseling the President and the Executive Branch on a wide range of issues. They, therefore, play an important role in shaping the policies and programs of the federal government. Today, an average of 1,000 advisory committees serve this purpose, providing advocates like you with a plethora of opportunities to further issues important to the PI community.

To ensure that various advisory committees' advice is objective and accessible to the public, the [Federal Advisory Committee Act \(FACA\)](#) was enacted in 1972. Through this act, Congress formally recognized the value of seeking the advice and assistance of citizens and advocates through advisory committees. FACA oversees many committees falling under the Department of Health and Human Services (HHS) umbrella relevant to the PI community, including the Advisory Commission on Childhood Vaccines, the Blood Products Advisory Committee, and the Advisory Committee on Heritable Disorders in Newborns and Children. Tools such as the [FACA Database](#) allow advocates such as those in the PI community to influence these committees and the policies they shape.

### Department of Health and Human Services (HHS)

Federal agency engagement on issues important to the PI community will most likely require engagement with HHS or one of its centers.

HHS is responsible for a large volume of proposed rules surrounding public health and healthcare issues and is, therefore, a reliable and consistent outlet for agency advocacy. HHS regularly develops regulations of consequence to the PI community, such as expanding research in therapies and ensuring patient health coverage. [HHS has 12 operating divisions](#), including nine agencies in the U.S. Public Health Service and three human services agencies. These divisions administer a wide variety of health and human services and conduct

lifesaving research for the nation, protecting and serving all Americans. Divisions that IDF typically engages with include CDC, CMS, FDA, HRSA, and NIH (see descriptions below). Each division consists of centers, offices, and institutes that focus on specific functions or areas of oversight. The [HHS organizational chart](#) includes links to each agency's chart showing the breakdown of offices, centers, and institutes. The centers are generally where rules and regulations are developed by staff experts in the particular area of focus. For example, the FDA has nine center-level organizations, including the [Center for Biologics Evaluation and Research \(CBER\)](#) and the [Center for Drug Evaluation and Research \(CDER\)](#), that focus on policies related to biologics and drug development and approval.

Opportunities for HHS and other agency advocacy generally entail engagement with staff from an agency center. In developing rules and regulations, the center staff will develop drafts shared with the public to allow those who might be affected to comment. All notices of draft and final federal rules are published in the [daily federal register available online](#). This database is searchable. The notices include a summary of the issues, dates of publication, deadlines for opportunities to comment, and instructions on submitting comments electronically or by mail or hand delivery. Submitting public comments is an effective and simple way to engage with large agencies such as HHS and allow the PI community's interests to be represented in regulatory discussions. Since there are innumerable draft rules and regulations published by HHS every week, the best way to identify what rules may affect the PI community is to work with IDF to focus your efforts.

#### Centers for Disease Control and Prevention (CDC)

CDC is the nation's leading public health agency. CDC focuses on a number of issues including infectious diseases, birth defects and developmental disabilities, and chronic conditions like PI. IDF engages with CDC on multiple issues like public health issues of importance to our community, such as the COVID pandemic, vaccination policy, and more.

#### Centers for Medicare and Medicaid Services (CMS)

CMS oversees the Medicare and Medicaid programs. IDF works very closely with CMS on issues pertaining to Medicare beneficiary access to PI therapies, particularly immunoglobulin (Ig) treatments. This includes the ongoing IVIG bundled payment demonstration program and implementation of Medicare's home infusion services payment.

#### Food and Drug Administration (FDA)

FDA is responsible for regulating large parts of the healthcare system including ensuring the safety and effectiveness of pharmaceutical drugs, vaccines, biopharmaceuticals, and medical devices. Many of the topics regulated by FDA have significant consequences to members of the PI community, such as avoiding shortages of Ig products and advancing novel treatments like gene therapies, which is why it is effective to advocate to this agency. The FDA has a range of resources that can be utilized by advocates in the PI community to share their experiences and influence regulations.

- [Patients Ask FDA](#) is a way for patients, caregivers, patient groups, patient advocates, and healthcare professionals to ask a question of the FDA about diseases, drugs, devices, vaccines, blood products, and biologics by utilizing the patient community web form. The form can also be used to request a meeting to share a disease experience, to better understand the FDA's regulatory work, or to request a [Patient Listening Session](#). The FDA is committed to responding to these inquiries in an effective and efficient manner.
- [Patient Listening Sessions](#) are done in partnership with the National Organization for Rare Disorders (NORD). These listening sessions can be FDA-requested – when the FDA has specific questions to

ask individuals – or patient-led – when a patient community wants to share their experiences with the FDA. These are small, informal, and non-public discussions that are a valuable opportunity for advocates to talk directly with FDA staff and share their experiences with PI.

- The [Patient Engagement Collaborative](#) strives to enhance patient engagement in medical product development and regulatory discussions by including patients' evaluations and perspectives of the FDA's engagement operations. This forum aids PI patients, caregivers, and patient representatives in being a meaningful part of discussions surrounding topics such as biologics, medical devices, and drugs.
- Advocates can influence the discussions surrounding the regulation of drugs and medical devices by being a part of the [Patient Engagement Advisory Committee](#). This Committee focuses on medical devices, the regulation of devices, and their use by patients. Membership in the Committee is by invitation only, but all meetings are open to the public. By contributing to the discussion of the benefits, risks, and outcomes of certain medical devices used by individuals with PI, advocates participating in this committee can influence the regulations on such equipment.
- [Patient-Focused Drug Development Meetings](#) facilitated by the FDA is another outlet for advocacy regarding drugs. The goal of these meetings is to better incorporate patients' voices into drug development and evaluation. As an expert in what it is like to live with PI, patients and advocates can provide a unique perspective on utilizing drugs to manage your condition. Participating in these meetings can make this perspective more clear to FDA regulators, and possibly influence the future regulation of drugs relevant to PI. IDF will reach out to the community when the opportunity arises for participation in a Patient-Focused Drug Development Meeting focused on PI.
- FDA is responsible for reviewing new drug and device applications to ensure that they are safe and effective for patient use. As pharmaceutical innovation has grown over the years, this has become an increasingly large responsibility. A few decades ago, the pharmaceutical industry and FDA jointly recognized that the FDA did not have enough resources to comprehensively review potential new products in a timely fashion. In response, they created the Prescription Drug User Fee Program for the industry to contribute resources to create an efficient process and ensure that FDA is adequately staffed for application reviews (for all, rather than for specific manufacturers or drugs). In 1992, Congress passed the first Prescription Drug User Fee Authorization, now known as PDUFA.

Each round of PDUFA applies for 5 years, after which industry and FDA negotiate, and Congress authorizes, new user fees and policy updates. Congress has subsequently created a number of [FDA User Fee Programs](#) for medical devices (MDUFA), generic drugs (GDUFA), biosimilars (BsUFA), animal drugs (ADUFA), and animal generic drugs (AgDUFA). During the PDUFA negotiation process, FDA hosts public meetings to discuss issues with industry and stakeholders. The current PDUFA is PDUFA VI and it expires at the end of 2022. Negotiations for PDUFA VII, including public meetings, are already underway. The FDA [PDUFA VII: Fiscal Years 2023 – 2027 webpage](#) includes detailed information on the current activities.

Health Resources and Services Administration (HRSA)

HRSA runs a number of healthcare programs including the nation's Newborn Screening program. This issue is very important to IDF as federal recommendations call for the screening of all newborns for SCID. IDF worked to get SCID onto the Recommended Uniform Screening Panel (RUSP) and then worked to pass legislation so all states test for SCID.

## National Institutes of Health (NIH)

NIH is the world's largest funder of biomedical research. IDF works closely with NIH, particularly the National Institute of Allergy and Infectious Diseases (NIAID), which leads research on primary immunodeficiencies (PI).

While not all issues addressed by the preceding resources are relevant to the PI community, keeping an eye on the actions of these groups and getting involved in consequential topics is an excellent way to influence the rules and regulations created by different agencies. There are a large number of tools available to advocates, so don't limit yourself to those explicitly listed here. This is a team effort, and IDF is always here to help navigate agency advocacy, whether it is with local, state, or federal entities. If there is ever a question about your advocacy, don't hesitate to ask IDF staff for assistance.

## Advocating with state and local agencies

### Departments of Human Services/Public Health

Visiting the website of your state or local health department can provide useful information and possible outlets for advocacy. You will find information about your rights as a patient, recent state and local regulations, as well as resources about various current issues. Many states even have an office for the healthcare advocate that can be useful for advocates like you.

After finding your [local](#) and [state](#) health department websites, advocates can decide the most effective way to engage with these agency officials. Whether this is through arranging a personal meeting, making a phone call, writing a letter, or commenting on rules or regulations, there are many ways to advocate for issues that are important to you and the PI community. Like legislators, state and local health officials look to advocates to educate them on important issues.

### State Pharmacy and Therapeutics Committee

Many states have a regulatory body that manages drug formularies within their Medicaid program called a Pharmacy and Therapeutics (P&T) Committee. A drug formulary is a list of treatments and medications that are covered by a prescription health plan or other public or private insurance plan. Immunoglobulin therapy, along with other existing or possible future treatments for PI, is a frequent topic in discussions surrounding drug formularies. P & T committees often conduct public meetings during which individuals can testify or supply verbal/written comments on issues of concern under the committee's purview, including the inclusion or exclusion of particular medications and treatments from their health plan's drug formulary. Additionally, many committees have members that represent consumer/patient interests, and these members are receptive to advocates who vocalize their views on an issue. Engaging with these committees can influence patient access to medications and therapies through Medicaid. To find out if your state has a P & T Committee, try searching your state health department's website. For more information about your state's P & T responsibilities as of July 2019 see the [Kaiser Family Foundation state health facts on State Medicaid Drug Review Responsibilities](#) published in April 2020.

### State Health Insurance Commissioner

All 50 states have a State Insurance Commissioner, and these regulators are meant to advocate for the people within their state. These agencies oversee the insurance industry with the intention of protecting patients and

consumers. Commissioners can play a large role in instituting healthcare reform and are therefore a useful resource to advocates in the PI community. Advocating directly to your state's Insurance Commissioner can be a very effective advocacy strategy for some issues. To find more resources and contact information regarding your state's insurance commissioner, visit the National Association of Insurance Commissioners (NAIC) [membership list](#). The NAIC coordinates with state insurance commissioners to institute standards and consistent regulatory oversight across states.

# Supplemental materials

Access supplemental materials located throughout the toolkit, all in one place.

## Advocacy basics

- IDF's video on [“How to Contact Your Legislators” \(and Regulators\)](#).
- IDF's [“How to Tell Your Story”](#) video.
- View [example testimonies](#) previously given by IDF advocates at a public committee hearing.

## Legislative advocacy

- [Website for the U.S. Congress](#).
- IDF's video on [“Advocating to Your State Legislature.”](#)
- Tool to locate and visit your [state legislature's website](#).
- Stay updated on the legislative initiatives and advocacy goals of IDF by [signing up for Action Alerts](#) to be notified when your voice is needed.

## Agency advocacy

- View the administrations of the Department of Health and Human Services (HHS) in this [HHS Organizational Chart](#).
- [Tool to locate the website of your local health department](#).
- [Tool to locate the website of your state health department](#).
- Information about your state's Pharmacy and Therapeutics Committee responsibilities can be found on the [Kaiser Family Foundation's facts on State Medicaid Drug Review Responsibilities](#).
- More resources and contact information regarding your state's insurance commissioner can be found through the [National Association of Insurance Commissioners \(NAIC\)](#).
- Information and background on the [Federal Advisory Committee Act \(FACA\)](#).
- The [FACA Database](#), which details the list of committees the act oversees.
- Resource that elaborates on [HHS and its 11 operating divisions](#).
- Link to the [daily federal register](#), where all notices of draft and final federal rules are published.
- Information about FDA's [Patient Listening Sessions](#).
- FDA's [Patient Engagement Collaborative](#) resource.
- Link to the [Patient Engagement Advisory Committee](#) and [Patient-Focused Drug Development Meetings](#), both facilitated by FDA.

## Identifying Existing Relationships with Elected Officials

### Personal Relationships

- **What does that mean?** You have a relationship with the elected official, such as a high school friend or a fellow churchgoer, or shared friendships.
- **What differentiates Close vs. Casual?** Close personal relationships would likely have the elected official's personal number and/or email. This could be a college roommate, someone who attended their wedding, etc. A casual personal relationship might be something like your children going to the same school as their children.

### Business Relationships

- **What does that mean?** You have a business relationship with the elected official, such as a former colleague, vendor, partner, etc.
- **What differentiates Close vs. Casual?** Close business relationships would likely have worked directly with the elected official in the past. In contrast, a casual business relationship may mean that you were indirectly connected from a professional perspective.

### Political Relationships

- **What does that mean?** You have a political relationship such as a former volunteer on a campaign, staff member while they were in office, host for political fundraisers, etc.
- **What differentiates Close vs. Casual?** Close political relationships would likely have worked in an official capacity with the elected official (such as a legislative aide) or were paid on their campaign, whereas a casual political relationship may mean that you were a volunteer who phone banked for them or volunteered your time on their behalf.

### Donor

- **What does that mean?** Someone who is a significant personal donor of the elected official/candidate, as this is important to distinguish on its own.

### Know Staff Member

- **What does that mean?** You know a staff member of an elected official, which is important to understand in the context of others who have direct relationships with the elected official.

## Key Contact

- **What does that mean?** You are a geographic or influential supporter. You may or may not have relationships with the elected official, but are important in terms of who the elected official represents.
- **Who does this entail?** This can be a Pastor of a large church in their district, a CEO of a large business, a journalist, etc.
- **How can you help as a key contact?** You can articulate how public policy affects your industry and/or help educate elected officials based on a group of constituents you represent.

## Generally:

- **Close** means that the elected official would recognize you if you reached out.
- **Casual** means they COULD recognize you but most likely would not

Good Morning/Afternoon,

My name is \_\_\_\_\_, I'm a constituent living in \_\_\_\_\_, and I have a primary immunodeficiency, or PI. This means that I was born with an improperly functioning immune system. I'm calling as a member of the PI community to ask Senator/Representative/Official (Name) to advance legislation/regulations that would support access to care for individuals with PI, like myself.

Individuals affected by PI often find it difficult to receive proper diagnosis, treatment, and specialized healthcare. They experience difficulties financing healthcare, finding educational materials, and locating others who share their experiences. Ensuring that those with PI have continuous access to adequate care is essential to the well-being and safety of these individuals.

(Insert personal experience)

I urge you to support the health and prosperity of individuals with PI by advancing legislation/regulations that promote access to care for people with PI, like me.

Thank you for your time and consideration on this important matter.

Points you can also mention if time allows:

- Individuals with PI have one of the over 400 rare, chronic disorders in which part of the body's immune system fails to function properly because of genetic or intrinsic defects
- There are approximately 250,000 people who are diagnosed with PI in the U.S., and thousands more go undetected.
- Fortunately, most people with PI can live healthy productive lives if they receive lifelong immunoglobulin (Ig) replacement therapy, a blood plasma product that helps prevent frequent and severe infections

## Addressing an Elected Official by Letter/Email

When writing to officials, whether using a handwritten letter or a typed email, it is important to utilize the proper forms of address – this helps convey the appropriate amount of respect to the official and the office they hold. Below are examples of how to correctly address an envelope, as well as a letter or an email. When writing to an official for your advocacy, be sure to utilize the formats below. For a letter, include a subject line and for an email, make sure to include a short description of what you are seeking.

### Envelope Example:

Your Name Your Address Your City, State Zipcode	The Honorable _____ Address of Official's Office City, State Zipcode of Official's Office
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### Letter/Email Example:

Date
The Honorable _____ Title/Role of Official Office Mailing Address
Re; Health Access for individuals with Primary Immunodeficiencies
Dear Representative/Senator/Mr. / Ms. _____,
Sincerely,
Your Name Your Address Your City, State Zipcode Your Phone Number

Dear Senator/Representative/Official (name),

My name is \_\_\_\_\_ and I am a constituent impacted by primary immunodeficiency (PI). As a member of the PI community, I am writing to ask Senator/Representative/Official (name) to advance legislation/regulations that would support access to care for people with PI.

Individuals with PI have one of the over 400 rare, chronic disorders in which part of the body's immune system fails to function properly because of genetic or intrinsic defects, and can affect anyone, regardless of age or gender. There are approximately 250,000 people who are diagnosed with PI in the U.S., and thousands more go undetected. Fortunately, most people with PI can live healthy productive lives if they receive lifelong immunoglobulin (Ig) replacement therapy, a blood plasma product that helps prevent frequent and severe infections.

Individuals affected by PI often find it difficult to receive proper diagnosis, treatment, and specialized healthcare. They experience difficulties financing healthcare, finding educational materials, and locating others who share their experiences. Ensuring that those with PI have continuous access to adequate care is essential to the well-being and safety of these individuals.

(Insert personal experience)

For these reasons, I urge you to support the health and prosperity individuals with PI by advancing legislation/regulations that promote access to care for these individuals.

Thank you for your time and consideration on this important matter.

Sincerely,

(Name)

## Identifying and Understanding Your Legislators

The most direct way to influence policy in the state or federal legislature is to advocate directly to your elected representatives. Therefore, before your advocacy can begin, the first step is to identify your legislators at the state and federal level and understand how they represent you. By inputting your zip code and address into IDF's "[Find Officials](#)" tool, you can identify all of your relevant state and federal legislators.

After searching your address using this tool, you will encounter a list of individuals sorted into federal and state officials.

The federal officials include the President and Vice President, two federal Senators, and one Representative. These are the officials that report to Washington, D.C. and represent you in Congress. The two Senators listed represent your entire state in the Senate, and are elected for 6 year terms. Each state has 2 Senators who represent it in Congress, regardless of how many individuals live in the state. The one representative listed serves solely your district in the House of Representatives, and is elected for 2 year terms. Each state has a different number of representatives in Congress, since this position is based on the population of a state. Districts are created so each representative serves about the same number of constituents, and your listed representative is who serves your congressional district.

The state officials include individuals that are responsible for solely state-wide affairs such as the Governor, Lt. Governor, Secretary of State, Attorney General, and State Comptroller. Additionally, this section displays the officials that represent your specific district at the state level, including your state senator and representative(s). These individuals report to your state capital and represent your district in the state government. While legislatures vary from state to state, most have a Senate and House of Representatives/Assembly/House of Delegates, similar to Congress. However, instead of electing two senators and one representative, you send only one senator and the number of representatives elected to serve your district will vary by state. State legislatures and the individuals you elect to them differ from Congress in that they only enact laws that apply to that state, instead of the entire nation.

It is easy to confuse state and federal officials, so just remember: federal officials represent your state/district in Congress with others from the whole country, but state officials represent your district in the presence of only others from your state. There are many healthcare issues that involve both state and federal laws and therefore, you may engage at different levels on similar issues. In addition, while Congress meets year round, with intermittent recesses, many, but not all state legislatures only meet for part of the year. You can find out about the specifics of your state legislature by utilizing the [NCSL State Legislative Websites Directory](#). All state legislatures have websites with a variety of resources including information on bills, elected officials, legislative calendars and legislative districts.