

### **Tips for calling your Member of Congress:**

- When dialing the main Washington, DC, number for your member of Congress, you will reach a staff assistant, likely a fresh-out-of-college (or grad school or law school) staff member.
- Give your name and organizational affiliation and/or where in the state you are from (they'll want to know you are a constituent).
- Ask to speak with the Senator's health care staff, ideally by name. The staff member with the title "Legislative Assistant" is most often the one you want (different offices use different titles...for some it is "policy advisor" or "counsel" if they have a law degree), though these staff are quite busy and can be difficult to reach. A Legislative Correspondent, Fellow, Intern, or Staff Assistant will be happy to take your call if you cannot reach the primary health policy point of contact. For the state office, you may wish to request higher-level staff such as the State or Director, but, again, you are likely to speak with lower-level staff.
- Be courteous in any case. It is the job of these staff to take note of constituent calls and pass along requests to the Senator or Representative.
- Note, for members of the House of Representatives, the title is "Congressman" or "Congresswoman" (though a few women may prefer the title "Congressman," e.g., see: <http://editions.lib.umn.edu/smartpolitics/2013/06/13/meet-the-three-house-women-who/>). When in doubt, you can also use "Representative."
- Your goal during the call is to say who you are and succinctly make your case to the congressional member with a clear "ask," or action item.

### **Sample Script for Patient Advocate Call to *Senators to Urge their Co-Sponsorship of the REGROW Act:***

- Hello, my name is \_\_\_\_\_. I am a member of [*organizational affiliation, if applicable*] in [*city*], [*state*].
- I am calling regarding an important health policy issue and would like to speak with the Senator's health care staff [*give name, if you have it*] if they are available.
- Senators Mark Kirk, Joe Manchin and Susan Collins have introduced S. 2689, the *Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act*.
- I urge [*name of your Senator*] to co-sponsor the REGROW Act and support its inclusion in, and passage as part of, medical innovation advancing in Congress this year.
- *Take 2-3 minutes to describe why this is important to you...for example, describe how these treatments could help you or a loved one with a particular illness, or how you or your organization would like to conduct/invest in cellular therapeutics research but have held back due to regulatory barriers, etc... make it personal! Then, share a bit of background on what cell therapies are, why they are not available to patients in the U.S. today, and why this legislation is needed. The below talking points are designed to help:*
  - Cell therapies, for instance extracting cells from a person's fat tissue and injecting them into another site in the body to help the body repair itself, represent tremendous promise for patients.

- Recent scientific advances in this field, including applications in cardiology, neurology, ophthalmology, and orthopedics, have the potential not just to treat diseases, but to cure them. For example, cellular therapy has the potential to halt the progression of degenerative joint disease in the knee or hip, or restore function to a failing heart or a damaged cornea. *[note, this is a general point, but you may want to say specifically how it could help patients like you...with applications for many types of chronic health conditions]*
- Unfortunately, due to significant regulatory barriers these treatments have never been approved by the Food and Drug Administration (FDA) and are not available in the United States.
- Professional athletes and other wealthy Americans travel to Germany, Japan, or elsewhere, to receive them. For the rest of us, safe and effective cellular therapies should be available right here at home.
- There are profound differences between inanimate chemicals and living human cells. In other words, cells are NOT drugs. Yet the FDA regulates them as if they were drugs, using non-binding guidance rather than a framework spelled out in law. This current regulatory structure simply does not fit for cells, which behave differently in the body than chemical drugs and are more personalized to individual patients.
- Furthermore, there is widespread evidence in medical literature of the safety of cellular therapies.
- What this legislation would do is clearly spell out in law a pathway that the FDA would use to determine which cell therapies must go through a full “biologics” approval process given their higher level of risk, versus which may be expedited through the process given they have demonstrated safety through Phase I and Phase II safety trials and show promise for efficacy in patients. These treatments would be granted conditional and temporary approval for five years at which time FDA would decide if they may proceed through the full approval process. The lowest risk treatments, defined as “practice of medicine” today, would remain as practice of medicine and avoid FDA regulation.
- This new framework is pro-patient, and pro-safety. Furthermore it should help the FDA ensure an appropriate level of oversight over safety and efficacy in patients. It would help to ensure clarity for doctors who want to treat patients using their own cells. It would generate more research and investment in the science of cell therapies.
- Thank you again for your time and for the Senator’s leadership on medical innovation. I hope we can count on [his/her] support for the advancement of cellular therapies in America and for patients like me.