

**Transcription: CHI Launches Podcast to Help Entrepreneurs Find  
New Sources of Funding**

*Industry Experts Help Navigate through the Complexities of Washington*



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**DAVID:** Hello and welcome to CHI's podcast. Today, I welcome Danielle Peters from Fabiani & Company and Conrad Clyburn, M.S., from The Clymer Group to the podcast. What we are looking to provide you today during the podcast is a discussion of the opportunities that now exist to find alternative forms of funding from government sources. The Recovery Act, so-called stimulus, has stipulated \$1.1 billion for comparative effectiveness research, as well as substantial funding for small startup biomedical companies. What we are offering today is a sort of GPS for navigating the complexities of Washington and this new political landscape to help you find funding sources that previously were not available.

Just to provide a bit of history on CHI, we were born out of the first effort in healthcare reform during the Clinton period in 1993 and we find ourselves still struggling with many of the same issues 16-years later. CHI currently is 270 members strong and our membership encompasses biomedical companies from early stage to established, as well as academic institutions. We are a hybrid organization that brings together academia and the commercial biomedical community in an effort to improve the environment for biomedical innovation in California. With us today is Danielle Peters of Fabiani & Company, an appropriations consulting firm with a variety of clients with the aim to improve access to government funding. Also with us is Conrad Clyburn, founding partner of Clymer Group, a consulting firm for emerging medical technologies servicing the private sector, government and academia both in the U.S. and abroad. Thank you, Dani and Conrad. So I am going to begin, Dani, by asking you, what is your take on the current environment in D.C.? What is available now to companies looking for financing from the government?

**DANIELLE:** Thank you, David, and thank you for inviting me to this podcast. The first important point to make is that the stimulus has created an entirely new scenario at the National Institutes of Health (NIH). NIH has seen a dramatic infusion of funding after years of declining budgets and the funding terms set for the stimulus funding in a lot of ways are very new, terms that have never been laid out before by NIH. They looked at things like job increases and ties to commercial partners as elements to consider for eligibility. There has been an obvious dramatic volume in response, which has been noted in the media that for

the Challenge Grants, for example, there are more than 20,000 responses and this can be very scary for a lot of companies that are interested in the stimulus funding, but it should not dissuade you from applying. An important point about that is that it is important to look at the broader funding picture. The stimulus has provided \$8.2 billion to the National Institute of Health that has to be spent between 2009 and 2010. The majority of that will need to be spent in 2010 and so if you are a company that has been denied a Challenge Grant or a bridge stand grant opportunity; it does not mean that the NIH is closing its doors to you in stimulus funding. It means that you should probably go back to different program officers, present different project opportunities and see how it might be aligned with NIH program opportunities moving forward because chances are you might be able to secure funding at the next time around.

Another important point is that it is good to look at the other funding opportunities. The Department of Defense (DOD) does quite a lot of work in life sciences research. While the DOD did not get funding in the stimulus for life sciences, there is quite a lot of funding at DOD and it is important as a life sciences company to be very open-minded in funding available from government trying to secure as many sources as possible.

Another point is that because of the stimulus at NIH, it has freed up NIH money to do other things that they might not have been able to do previously and so we have had clients that, for example, were turned down for standard grants that they had submitted through NIH and that were approached by NIH again because the stimulus has freed up that money to then pursue those recent opportunities. The bottom line is to continue to engage with NIH to keep those opportunities open.

The last point I just wanted to make is that in approaching NIH in terms of improving your chance of securing funding, it is important to look at your internal advocates within NIH and your external alliances, which are with academic partners that might have a long history of securing funding from NIH and aligning yourselves with them together with speaking to your internal points of contact at NIH can really improve your chances of securing funding.

**DAVID:** That is terrific, Dani. Conrad, what advice do you give your clients who are seeking new funding sources from the government?

**CONRAD:** Well, I could not agree more with what Dani said as an overview. What I want to add is that the most important thing I think the individual business or entity should do is to come up with a well-defined and methodical strategic plan for approaching this market. That would include, at least from The Clymer Group perspective, a six-point approach. One is to track the programs in detail, prioritize the promising targets among the different programs and Dani mentioned the attractiveness of the funding at NIH and at DOD, but one of the real opportunities that entities have today is that the funding is spread among a number of different programs and agencies. You have the community clinic health information technology appropriation that is being managed out of Health and Human Services (HHS). One should look at the supplements to existing awards; both are competitive supplement administrative supplements to add to their existing interactions with NIH. Dani mentioned the comparative effectiveness research (CER) grants, which is a whole new area; \$1.1 billion spread between the Agency for Health Research and Quality (AHRQ), HHS and NIH. One of the attractive features of the CER, as they are beginning to call them grants, is that those

have not yet been, the announcement has not yet come out and probably will not until September for the first round of comparative effectiveness research grants and the Institute of Medicine (IOM), published a report at the end of June for the president and Congress suggesting 100 of specific topic areas for comparative effectiveness research. So it would be useful for one to get hold of that report, the IOM report, on comparative effectiveness and to study those topics. There is training money that is at the Office of the National Coordinator for Health Information Technology. They have got a total appropriation bump-up of more than \$2 billion and there will be training centers that will be set up on a regional basis that will help with the adoption of electronic health records and that is another area to take a look at and then, of course, HRSA also has some separate programs.

The third area that I would urge the interested entity to look at is in building relationships at the federal, state and local levels with the program managers for the stimulus funding. The program managers within government are under great pressure to obligate this money by the September 2010 timeframe and the more information they have on the attractiveness of an entity's offering, the better positioned it will be.

I think that, four, it is important to understand the procurement process at each of those levels—the federal, state, and local levels.

Five, to the extent that one has validating data for their product or service, that should be ready to go and made available and then, last, is to develop a methodical, written strategic plan. I think one of the points that Dani made that is very important is that this money is both 2009 and 2010 money. So the first round should not discourage one from seeking a more focused approach with the second round of funding that will come in 2010. So this is a marathon and not a sprint and one should approach it in a methodical way.

**DAVID:** Thanks, Conrad. Dani, what are some of the misconceptions that your clients have or mistakes that you have seen people make in seeking government funding?

**DANIELLE:** Well, I think the bottom line is that companies are more likely to succeed if they engage with government program officers and government investigators and government-funded investigators before they submit an application to government for funding and this is government wide, not just NIH. If you do engage these program officers before you submit, you are able to get their insight about how your technology fits in with their policies, their programs and priorities and you can shape your submission in a way that accommodates those different preferences; obviously in a way that also makes sense to you as a company, that makes sense to your programs moving forward, but the first step that you can do is prepare a technical presentation that you can give to subject matter experts that are government subject matter experts, the program officers that dole out these funds for these awards, but there are lots of other government resources available. There are lots of government laboratories across the United States. There are government-funded consortia in all sort of research areas from cancer to metabolism to genetics, I mean all sorts of areas, and all these different groups have an entry point into government and they can be another set of eyes that can look at your presentation, look at your technology, and give you insight about how it can be structured in a way to better position you for that government funding.

The second aspect is that companies are much more likely to succeed if they use their allies and partnerships effectively. Each life sciences company has a whole array of academic partners, board members that might have different entry points, and it is a matter of using them at the right time and in the right place; talking to the different academic partners that you have, understanding what experience they might have had with NIH before and what entry points they might have and partnering with them. If you look at all the different awards that were made through NIH through the stimulus so far, the vast, vast majority are going to universities that, in my opinion, are a problem. I think much more of the money should go directly to companies, but a lot of that money is actually to universities to be shared with companies and so the point is, using academic partners that might have a background, a history of getting government money will position you down the line because the NIH has to give out money so quickly, they are going to give it out to people they can trust and so align yourselves with academic partners that have that background can probably position you much better. And so those are the two different aspects I would think that are really the factors that help companies get money more than others.

**DAVID:** Those are excellent points. It has been said that there is so much government money available through the stimulus and through the TARP and so forth that a trillion has become the new billion, but the question is there is a lot of government funding available and yet people for whom this is new need to decide whether it is an opportunity for their company, an opportunity for them or not and if you are new to the process, how do you know whether this is a valuable way to spend your time? What is the first step, Conrad, that you would take in answering that question whether it is an opportunity for my company?

**CONRAD:** Well, this comes down to point number one, which is it is an investment that every organization must make to study the programs in some detail to ensure that there is a clear intersection between their technologies and their offerings and actual language in the announcements and that can be done in a number of ways. The federal government and many of the states have established web pages that provide guidelines and valuable types of matrixes of the different opportunities that are available. I think Dani made an excellent recommendation in terms of outreach to government relations or managers that may be available either in the private sector and, of course, once leveraged, the local congressional office that is in their district and at the state level in the economic development agencies and authorities. There are people who are now specializing and deciphering where those opportunities are, but I would go one step further to also associate myself with Dani's point about partnering.

One of the things that we have noticed is that particularly since this broadcast is emanating from the West Coast, that there are opportunities for West Coast companies and organizations to do some outreach to some of the East Coast organizations that have a lot of experience in working with the federal agencies and in executing and securing SBIR grants. Quite often, the East Coast companies and entities are not that experienced at what I think the West Coast has become very good at, which is achieving a mass market scale by working through venture capital so that dichotomy in experience, the West Coast companies and entities that are very experienced in working with private equity and venture capital, partnering with East Coast companies that have become quite skilled at interacting with the federal agencies, particularly in the SBIR and the STTR programs, I think also is a new and unique opportunity. Does that make sense?

**DAVID:** That is terrific. I just want to reemphasize the importance of knowing your local member of Congress. All members of Congress have district offices and those offices are for constituent relationship building and so the ability to talk to the staff there, many of them young, but they are go-getters. They are eager to build relationships with companies in their districts and that can be a real wedge into finding government funding. One challenge I think with seeking this type of funding is that when you look at it at first, it seems to be highly specific and companies have to commit to a program very early on. Dani, how do you advise companies to deal with, for example, these Challenge Grants that look so specific?

**DANIELLE:** And that is the important point, that government funding is not for everybody and it might not be for every program. It is important for a company to look at its pipeline, look at its technology, and the various different applications that it has. Look at its assets and really understand which ones would benefit the most from government funding, from the nondiluted funding that government brings. It is mostly likely not your lead product and that is just because government's funding tends to shift from time to time. As we see, there's this delay in government funding and it is tough to go back to your investors and explain that your lead product is in question here because you are waiting on government funding. So I would say it is probably a better choice to focus on assets that you are not really moving right now and particularly a lot of companies right now are, in light of some economic challenges, are choosing to do that, to put those aside. Those might be the best assets to look at for government spending, ones that if you were to advance it further that could put it in a position that is really ideal for commercial partnerships or for an acquisition and that is where government can be ideal. It is frustrating for a lot of life sciences companies to look at these Challenge Grants and other government funding and find it to be too restrictive, but that is why the initial consultation with government is so critical because once you talk to them and have them develop an appreciation for your technology, you might realize that there is a little bit more wiggle room than you might otherwise have realized just in looking at the funding opportunity and they might share with you some flexibility that they have on their end and how you can shape it that would accommodate the government, but also accommodate your commercial strategy.

**KIRK:** And if I can add to what you are saying is that there are some new programs that are associated with the stimulus package that do have some built-in flexibility. I would point to two, in particular; the biomedical research developed and growth to spur the acceleration of new technologies program, which is an NIH program specifically targeted to small business, could be of great interest. It has very broad language. It is soliciting applications to address the funding gap between promising research and development and the transition to market, you know what we call the "Valley of Death" by contributing critical funding needed to pursue the appropriate milestones towards ultimate commercialization and that is about as broad as you can get as far as language for a medical technology company. And then another program that is called ARRA small business catalyst awards for accelerating innovative research, also out of NIH, which has similarly broad language. So I guess what I would say would come back to the original point is that the analogy that we have been using with our clients is that you may want to think about the stimulus funding as a large herd of animals and that you do not want to just run at the herd in an undifferentiated way. What you want to do is to seek out a specific animal to go after that is a good fit for the individual business

or entity, but if one very carefully examines the number of opportunities, there is a good chance that you could find that intersection.

**DAVID:** We have been talking a lot about what companies can do to identify sources of government funding, but on the other side, we have managers at NIH and other federal agencies who are responsible for distributing in the most responsible way government money, government grants. What advice, Dani, would you give to agency officials who are looking to do the best possible job in allocating government resources?

**DANIELLE:** I think my one piece of advice is to not hold back on giving money to companies. I mentioned earlier that it is great that the NIH has given quite a bit of stimulus money so far, but the majority of the funding, at least what's listed, is going to universities and I think that it would be great to promote the value that NIH brings to innovation in companies and jobs and trying to make more announcements to and make funding to companies directly. I think another aspect that the NIH has to understand, which gets the point of having some of these funding opportunities being so narrow is that they do have to understand that for companies to excel, the programs have to be commercially oriented. They have to be product oriented and a lot of the accusation about NIH is sometimes it is not so product oriented. So I think that more funding opportunities that are structured in that way could be tremendously beneficial both to the companies, but obviously to the country because ultimately in the end, we will have more product and we will have more jobs and so I think that that is an important aspect that NIH needs to consider maybe more so than they are now, but I think they're getting much better at it, in my opinion.

**DAVID:** Let me just say in conclusion a few points. One is do your homework, build relationships as you do in any commercial enterprise, relationships with agency officials, with legislators, with the staff of your local member of Congress. I think in our industry, companies have a good story to tell. Everyone wants cures. Everyone wants more biomedical R&D for unmet medical challenges. No one wants a bridge to nowhere project. So our companies have a great story to tell. Make the connection to jobs, the economic growth. It is important to have validation from agencies like NIH and, most importantly, if you have integrity in what you are doing, it is really going to make a difference for patients, you can make a great case for funding your innovation. So I would like, again, to thank Dani and Conrad for joining me today and thank you, the listeners, who are subscribing to CHI's podcast. Remember to check back on the CHI website regularly for upcoming events, podcasts, and publications. That is [www.CHI.org](http://www.CHI.org). Thank you again.