

What we need from the next administration

July 15, 2008 By [Paul Dalton](#)

✖ With apologies (and fawning ?I am not worthy? respect) to [Bill Nye](#), at Project Inform, I am the science guy. My daily grind is journals, conferences, clinical trials and advisory boards. I swim in a world of hard data, and I like it that way. As complicated as confidence intervals and statistical power can be, numbers are comfortingly straightforward.

Project Inform is fortunate to have two highly respected and effective public policy experts - Ryan Clary and Anne Donnelley. They are our policy gurus- managing to have both a wonk?s understanding of the nuance of legislation, and an organizer?s skill in forging alliances and building bridges.

I don?t envy Ryan and Anne. Their work is much harder than mine. I like my little clean world of molecules, informed consent documents and peer review. Politics makes organic chemistry look like basket weaving 101.

Sometimes though the neat and tidy divisions between treatment advocacy and public policy don?t hold. Public policy influences science and vice versa. So, this presidential election season I have been asked to think about what I, the science guy need from the next administration. Not knowing who will be in the Oval Office, or what the balance of power will be on the Hill, I will focus on the one thing I really, really need from the next administration- no matter who wins in November.

I need an administration that respects science. I need an administration that allows science to speak for itself, and let?s the scientific process run itself with minimal interference from ideologues.

Global warming, fuel prices, world food shortages, and the aging population are a few examples of topics likely to be widely the next few months, and where science should be at the forefront.

While I doubt that HIV/AIDS will get much airtime, the attitude and behaviors of the next administration toward science will impact people living with HIV/AIDS- in the US and world wide. Four areas where this impact might be most felt by our community are the National Institutes of Health, the Food and Drug Administration, stem cell research and needle exchange.

The NIH

The next administration needs to adequately fund science and let scientists drive the research process. The National Institutes of Health houses much of the government's research efforts aimed at HIV/AIDS. NIH's Division of Acquired Immune Deficiency Syndrome (DAIDS), headed up by Carl Deffenbach conducts and funds research ranging from basic science to vaccines to prevention and treatment.

Some argue that HIV/AIDS receives a disproportionate amount of Federal research funding. While it is true that HIV/AIDS receives a large share of research funds, this research helps advance and inform work done in many biomedical and social research areas. For example, too AIDS relatively little research focused on the immune system, leaving our body's second most complex system largely mysterious. Our understanding of the immune system has grown by leaps and bounds over the past 30 years, driven largely by HIV/AIDS research. This research has benefitted many areas of medicine, from autoimmune disorders to heart disease.

The NIH needs to be a funding priority. Equally important, their research priorities must be driven by science more than politics. In the wake of the World Trade Center attacks, there was a major push toward "bioterrorism" related research. While such research is important, fear should not deflect us from fighting the very real problems we face, including HIV/AIDS.

The FDA

We need an administration that will allow the FDA to work independently, to balance its primary job of ensuring drug safety with the need to develop new and better treatments particularly for serious illnesses.

The Food and Drug Administration (FDA) has suffered some criticism lately over drug safety issues. The primary role of the FDA in regards to pharmaceuticals is to ensure safety. From Fen Phen to Vioxx, there have been times when they have been less than successful. This has led the FDA to become somewhat risk-averse. This is okay, as long as it doesn't preclude creative approaches to evaluating new drugs.

In recent years, most new HIV drugs have been developed using very similar trial designs. The basic design had worked quite well, and led to the introduction of a number of powerful and well tolerated new HIV drugs. This design is not workable anymore, for a number of reasons.

Project Inform, along with activist coast-to-coast have been meeting with FDA and industry for the past year-plus to tackle this issue head on. Recently, The FDA has shown some openness to new ways of developing HIV drugs. We hope this trend continues.

The FDA has experienced some direct politically motivated interference from the current administration. Most famously when their advisory committee voted to expand access to the birth control measure, Plan B, the White House intervened for political, not scientific reasons. This kind

of interference compromises the FDA's independence and undermines its work. The next administration needs to allow the FDA's process to work, as free of political considerations as possible.

Stem Cells

One more area we need a new direction from the new administration on is stem cell research. Stem cells hold tremendous promise for many diseases including HIV/AIDS. The current administration has greatly restricted federally funded stem cell research, again for political and not scientific reasons. Federally funded scientists, including those working for or funded by NIH, must be allowed to fully research the life saving and healing potential of stem cells, free of politically based constraints.

The promise of stem cells for HIV was never more evident than this year's CROI conference. As Project Inform wrote about, an HIV positive German man received a stem cell transplant due to cancer. A matched donor was found for him who also had an unusual genetic trait that has been shown to make people highly resistant to HIV infection (called the homozygous Delta-32 allele). They wanted to see if the stem cells would take hold in his body and alter the course of his HIV disease.

It did. He was taken off his HIV drugs at the time of the transplant- and had not needed to restart over a year later. His HIV viral load was undetectable by both standard methods and more sensitive, pro-viral DNA- tests. While nobody has said this man is cured, the stem cell transplant seemed to have a significant impact on his HIV disease.

The Federal restrictions on stem cell research have had a chilling effect of the entire field. Some researchers have moved their work to more friendly environments. In some cases, governments- like the State of California- have stepped in to the breach to stimulate stem cell research. As administration that encourages cutting edge science would be ideal; one that doesn't aggressively thwart it would at least be an improvement.

Needle Exchange

Science doesn't often lend itself well to bumper stickers, but needle exchange does indeed save lives. By making clean needles available to people who need them, needle exchange programs have been shown to reduce HIV infection rates among needle users and their sexual partners.

With HIV infection rates stubbornly high, proven prevention methods should be supported. Congress and the White House have treated needle exchange like a political hot potato. Federal funds are barred from supporting needle exchange programs in their back yard of Washington, DC- an epicenter of the epidemic. The Bush administration has opposed efforts to expand needle exchange programs both in the US and abroad.

The objections to needle exchange are largely moralistic. If public policy was rooted in science there would be no barriers to needle exchange. Needle exchange programs studied worldwide have been shown to be effective and, contrary to their opponents' rhetoric, not to increase rates of drug use. The next administration must defer to science over narrow views of morality and support needle exchange.

The worlds of science and politics are often quite foreign to each other. Few politicians come from scientific disciplines, and most scientists don't relish the world of politics. The scientific process works best unfettered from the world of partisan politics. Project Inform looks for a new kind of leadership from the next administration, one that respects science and the scientific process and does not subvert it for political gain.

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