LETTERS

edited by Jennifer Sills

Keeping an Eye on the Prize

I WAS VERY DISAPPOINTED TO FIND OUT (“Fame inflation,” Newsmakers, 1 February, p. 553) that I, like Steven Running, am not a Nobel laureate. According to the “Dear colleagues” letter I received from Ogunlade Davidson and Bert Metz on behalf of the IPCC, I am indeed a Nobel laureate, albeit perhaps along with many, many others. The letter says, “You no doubt have heard about the award of the Nobel Peace Prize to the IPCC, jointly with Al Gore of the USA. This makes all of you a Nobel laureate and we, as co-chairs, want to congratulate you wholeheartedly with this exceptional recognition.” Additionally, a beautiful Nobel Peace Prize certificate with my name on it now adorns my wall. Although the financial remuneration has not yet arrived, I have enjoyed the celebrity status associated with the honor.

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Epigenomics: A Roadmap, But to Where?

RECENTLY, THE DIRECTOR OF THE NATIONAL Institutes of Health (NIH) allocated $190 million for an “Epigenomics” Roadmap initiative (1). As investigators in this area, we endorse the idea that chromatin biology is an appropriate, if not essential, area for the NIH to support, not only for its fundamental biological significance but also its relevance to human disease. Nonetheless, we believe that this initiative, at least in its current form, will not yield significant benefits. If the use of the term “epigenome” is intended to equate the value of this Roadmap initiative with the Human Genome Project, it fails on several grounds.

First, it does not consider our current understanding of the roles of sequence-specific DNA recognition events and transcriptional networks in controlling epigenetic changes. A multifaceted effort that elucidates transcriptional circuits that tell us where and when signal-responsive, sequence-specific regulators function would be more useful for understanding cell type programming.

Second, merely cataloging modification patterns offers comparatively little new or useful information. We already know that most genes are associated with one of a few patterns of chromatin modifications and that the patterns themselves do not tell us how that gene is regulated or how its expression state is inher-
group or the case (affected) group. It may also be possible to statistically infer whether a relative of the individual is a member of the case or control groups. The method requires having an individual’s high-density genotype data in hand from another source. Though the specific identity of the individual who was the source of the data could only be determined if that source were known through other means or reference data, this discovery nonetheless has implications for how these summary data should be protected. As a result, NIH has removed from open-access databases the aggregate results (including $P$ values and genotype counts) for all the GWAS that had been available on NIH sites (such as dbGaP and CGEMS). NIH intends to move the aggregate genotype data to the controlled-access database, where there is a firewall as well as protections and policies in place for appropriate data access, including review and approval of data access requests. The new finding does not have the same implications for data available through controlled access, and NIH access policies for individual-level genotype and phenotype data have not changed.

Sharing genomic data and, particularly, allele frequencies has become common practice, if not an imperative, in science. Yet, the protection of participant privacy and the confidentiality of their data are of paramount importance. These new statistical approaches have implications far beyond NIH data-sharing policies, as aggregate GWAS data have been provided in publicly available form in many other ways, including other research databases and Web sites, journal articles and other publications, and scientific presentations. NIH urges the scientific community to consider carefully how these data are shared and take appropriate precautions to secure aggregate GWAS data in order to protect participant privacy and data confidentiality.

In short order and over the coming months, NIH will work with our advisory groups and the wide range of stakeholders related to GWAS to further explore and address the policy implications of this finding. We call on our colleagues in the scientific community to join us in these important deliberations.

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References

Closing a Loophole in the FDA Amendments Act

IN THEIR POLICY FORUM “MOVING TOWARD transparency of clinical trials” (7 March, p. 1340), D. A. Zarin and T. Tse caution that “FDAAA 801 still leaves areas of ‘opacity.’” We would like to point out another loophole: FDAAA 801 will only cover future drugs. The thousands of drugs on the market today, including the controversial examples cited by Zarin and Tse, will be grandfathered in and not covered.

Whether this matters to public health depends on whether today’s uncovered drugs will soon become obsolete. To address this

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CORRECTIONS AND CLARIFICATIONS

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question, we examined prescribing trends over the past 8 years for three drug classes cited by Zarin and Tse. From listings of the top 200 drugs (1) for the years 2000 through 2007, we extracted the numbers of prescriptions dispensed in U.S. retail pharmacies. Within these three drug classes, we totaled the annual number of prescriptions of brand and generic drugs that had been first marketed in the United States within the past 20 years.

We found that oral drugs for diabetes, including Avandia (2, 3), are (as of 2007) being prescribed 265,000 times each day; their prescribing rate has been increasing 8% annually. Cholesterol-lowering drugs, including Zetia (4) and Baycol (5), are now being prescribed 528,000 times each day; this rate has been increasing 10% annually. Finely prescribed 265,000 times each day; this rate has been increasing 22% annually.

These data indicate, in our opinion, that these drugs—none of which will be covered by FDAAA 801—are widely prescribed and unlikely to disappear soon from the U.S. market. It is unfortunate that FDAAA 801 grandfathers in currently marketed drugs.

While this act provides for a registry and results database that is prospective, we need one that is also retrospective. Such a database has in fact existed for decades at the FDA (7). If we can make better use of it, a solution to this area of “opacity” lies readily within our grasp.

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includes a provision whereby the Secretary of Health and Human Services may require registration and results reporting for certain clinical trials of FDA-approved drugs, biologics, and devices retrospectively to protect public health (trials completed up to 10 years prior to enactment of the act, i.e., September 27, 1997). Finally, FDAAA 801 explicitly provides for consideration, during the 3-year rule-making process, of mandatory results reporting from certain clinical trials of drugs, biologics, and devices not approved by the FDA. Such a policy would substantially broaden the evidence base available to the public.

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Big Payoffs Possible for Small-Molecule Screening

IN THE NEWS FOCUS “INDUSTRIAL-STYLE screening meets academic biology” (8 August, p. 764), J. Kaiser presents the discovery of several potential small-molecule therapeutics and probes for cellular function along with skeptical views from industrial scientists questioning “whether this massive effort is worth the time and money.” The goals of the pharmaceutical industry and academia are very different. Industry scientists are focused on discovering a highly specific and potent compound that can benefit human health. Academic scientists focus on finding compounds that can reveal novel cellular mechanisms, a basic tenet in chemical biology (/). It is this pursuit that allows the academician to foster student learning and interdisciplinary collaborations with faculty that could lead to a novel biological probe or a potential therapeutic. The current $100 million-per-year funding from the NIH Molecular Libraries Initiative (MLI) is a wise investment in the training of future scientists and teachers. Students working with faculty mentors on these screening efforts learn how to solve problems across all areas of science and mathematics; indeed, the “challenge of merging two cultures—biologists and chemists” is an opportunity for a better education (2). Such an interdisciplinary approach to science education is timely, given the recently passed Public Law 110-69, “America Competes Act,” which includes appropriation of $896 million for “education and human resources” (3) that will promote the training of future science and mathematics teachers. Regardless of the skepticism, I believe that the NIH MLI could “pay it forward” to our society in many ways.

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References

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Science 322 (5898), 44.
DOI: 10.1126/science.1165490 originally published online September 4, 2008

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