



LETTERS

Edited by **Jennifer Sills**

Sanctioning to extinction in Iran

The lifting of economic sanctions on Iran in early 2016 raised hopes among conservationists that much-needed support would finally be made available (1) to protect the country's unique and threatened biodiversity (2). Unfortunately, on 4 November, economic sanctions were reimposed, likely leading to serious repercussions on biodiversity conservation (3).

Conservation of threatened biodiversity often relies heavily on international cooperation, which can become impossible under economic sanctions. Sanctions reduce opportunities to transfer international expertise and skills (2) and erect barriers to international financial support (4), which together limit the capacity of conservationists within sanctioned countries to enact effective conservation interventions. These factors have hampered conservation efforts to save the critically endangered Asiatic cheetah (*Acinonyx jubatus venaticus*) (5), the population of which is confined entirely to Iran and now numbers fewer than 50 individuals (6).

Rightly, international law enshrines peoples' right to humanitarian relief during conflicts and embargos (7). Recently, the United Nations has taken steps to protect globally important cultural heritage sites during conflict (8). Biodiversity, which has global value and is critical for human well-being (9), requires similar protections. The UN Convention on Biological Diversity (CBD) (10) enshrines international

responsibilities to safeguard ecosystems and biodiversity. Additional measures are needed to ensure that countries meet their CBD obligations during conflicts. Exemptions should allow the international cooperation and resources needed to save threatened species. Countries must also be required to adhere to their responsibilities (11) to safeguard conservation personnel ("In letter, researchers call for 'fair and just' treatment of Iranian researchers accused of espionage," R. Stone, 21 November; <https://scim.ag/IranLetter>). Without such measures, we may see the first continent-wide extinction of a big cat, the Asiatic cheetah, in modern times (12).

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10.1126/science.aav8221

Defending the return of results and data

The National Academies of Science, Engineering, and Medicine recently published a committee report on return of individuals' research results and data, proclaiming commitment to increasing research participants' access (1). Our Policy Forum, "Return of results and data to study participants" (12 October, p. 159), showed that the report's recommendations would actually constrict participants' access, eroding crucial federal privacy protections and rejecting two decades of consensus recommendations on how to return results safely and ethically. In their Letter, "Standardizing return of participant results" (J. R. Botkin *et al.*, 16 November, p. 759), committee members defend their report. Their letter again shows misunderstanding of the law and reluctance to trust research participants with access to their own data and results.

The committee's report is based on a disputed position by the Centers for Medicare and Medicaid Services (CMS), which maintains that a laboratory must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in order to return individual-specific results (1). Unfortunately, the report's Statement of Task directed the committee to evaluate current regulations and recommend alternatives but prohibited them from analyzing "the scope or applicability of CLIA" and whether this CMS position is correct (1). Our Policy Forum showed that the CMS position is incorrect. Under the CLIA statute and regulations, CMS can require CLIA compliance only if a research laboratory provides information for clinical use; other purposes fall outside CLIA, including providing results to trigger clinical confirmation or allow participants to contribute data to further research. Basic administrative law analysis shows the defect in the CMS position.

Botkin *et al.* claim that "there is no

consensus” about the defect in CMS’s position and that it “has not been overruled by the courts.” However, the federal Secretary’s Advisory Committee on Human Research Protections (SACHRP) found the CMS position “at odds with the plain language” of the CLIA regulation (2), which follows the statute’s language. Neither source that Botkin *et al.* cite actually defends the CMS position under the administrative law principles on which our Policy Forum relied. Such legal analysis is based on established administrative law doctrines and does not depend on consensus, but on the plain language of enacted statutes and regulations.

One also cannot assume that a federal agency’s position is legally correct simply because it has not yet been “overruled.” Various legal doctrines limit courts’ ability to hear challenges to agency position statements (3). It is naïve to assume courts promptly “overrule” errant agencies.

Botkin *et al.* claim that “many research institutions” are following the CMS position but cite no support (and the report indicates that others return non-CLIA results). Whatever some institutions may be doing to minimize risk in a confusing legal landscape says nothing about what an

Academies committee should recommend normatively as a solution. To devise sound recommendations for law and policy, the committee needed to fully analyze the relevant statutes and legal options. We did not urge “ignoring” the CMS position; we urged the opposite—thorough analysis. The committee did not provide this, as the Statement of Task forbade it.

Botkin *et al.* also defend their recommendation to amend the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to exclude much research data and results from the individually accessible Designated Record Set. This similarly suffers from inadequate legal analysis. The HIPAA access right clearly applies to research information, including from non-CLIA laboratories. As SACHRP notes, the Designated Record Set may include test results “from non-CLIA-certified research laboratories” (2). And when CLIA-confirmation is unavailable, “the results should still be provided upon the individual’s request,” as this is “required by law” (2). Congress extended HIPAA access rights to genetic information, including from research (4, 5). People need access, regardless of data quality, to assess their privacy risks.

As our Policy Forum and others recognize, individuals have strong interests in access to their research results and data, especially as research transitions to more participatory models (6–8). The barriers advocated by the committee are based on inadequate legal analysis, inaccurate synthesis of current guidelines, and refusal to trust research participants. We urge regulatory agencies, research institutions, and investigators to perform a full analysis of the law and literature before acting on the recommendations of this Academies report.

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10.1126/science.aaw1851

Working governance for working land

In their Review “Landscapes that work for biodiversity and people” (19 October, p. eaau6020), C. Kremen and A. M. Merenlender discuss techniques that can preserve both ecosystem services and biodiversity in landscapes that have been modified by humans. They suggest that working lands can form useful peripheries to core protected areas. However, if appropriately managed, working lands can do more than just provide appropriate land use around strictly protected areas. Some working lands and less-strict forms of protection afford comparable conservation outcomes to state-controlled protected areas (1, 2).

Whether as core or periphery, the critical challenge is to understand what governance works best to conserve the biodiversity of private, communal, and state-managed resources (3, 4). On working lands, the potential for biodiversity-rich management depends on who owns and controls land or water use, on what terms, and with what objectives. Rights to resources, the rules controlling their use, and the arrangements by which these are forged, enforced, and revised are critical to conservation success (5, 6). Even as there are calls for improved governance, knowledge about the relative effectiveness of different governance arrangements, and the political and social coalitions necessary to support them, remains in its infancy.

Rural people play a vital role in the protection of biodiversity in most landscapes, both within and outside protected areas (7, 8). The conservation challenge lies in identifying what specific forms of governance arrangements will work in particular locations and with which rural peoples. Models must vary; we should design governance arrangements for different contexts. Only solutions tailored to the particularities of each region can win the enduring social

and political support needed for maintaining biodiversity in the long term.

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10.1126/science.aaw8452

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Science **362** (6420), 1255.
DOI: 10.1126/science.aav8221

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