ISSUES AND IMPLICATIONS ASSOCIATED WITH MAINTAINING A RHESUS MONKEY BREEDING COLONY WITHIN THE ACE BASIN NATIONAL ESTUARINE RESEARCH RESERVE

Identification of Issues Associated with Maintaining a Lease Agreement Between the South Carolina Department of Natural Resources And LABS of Virginia in support of a Rhesus Monkey Breeding Colony on Morgan Island, South Carolina

7 August 2002

Background

In the Spring of 2002 the South Carolina Department of Natural Resources (DNR) obtained ownership of Morgan Island, an island of approximately 4000 acres (approximately 400 of which are highland, the balance of which is marsh and intertidal areas) located in northern Beaufort County, SC. Morgan Island had been slated for development, and the previous landowner had surveyed the island and had begun the process of subdividing it into 64 residential lots before the DNR stepped in and purchased it. Morgan Island was purchased with funds provided from several sources, the majority of which were federal appropriations through the National Oceanic & Atmospheric Administration (NOAA) in support of land acquisition for the ACE Basin National Estuarine Research Reserve (NERR). The DNR operates the ACE Basin NERR to provide a natural outdoor laboratory for estuarine research and education.

Financial Arrangements (Lease and Property Transfer)

Ownership of Morgan Island is encumbered by an existing and longstanding lease that has been negotiated between the previous landowner (and the seller of Morgan Island to the DNR), Morgan Islanders, Ltd., and LABS of Virginia (hereinafter referred to as "LABS"). LABS has held a lease on Morgan Island since 1979 for the purpose of maintaining a breeding colony of rhesus macaque monkeys (presently estimated to number between 2500 and 3000 animals), which are used for biomedical research and testing. LABS maintains the monkey population under contract with the United States Food and Drug Administration (FDA). The FDA actually owns the animals.

The Morgan Island lease was last renegotiated in December 2001 and expires on 31 December 2004, though as landowner the DNR may terminate the lease effective on any date after 30 September 2004 provided that DNR so notifies LABS at least six months in advance of the effective date of termination. Rent payable for use of Morgan Island for the following time periods is:

1/1/02 – 12/31/02	$325,000
1/1/03 – 12/31/03	$787,500
1/1/04 – 12/31/04	$787,500

According to the terms of the property transfer between Morgan Islanders, Ltd. and DNR, Morgan Islanders, Ltd. will receive and retain all rents paid under the lease for calendar year 2002 and 2003 and the first $175,000 of rents paid for calendar year 2004. These receipts constitute the balance due to Morgan Islanders, Ltd. for the island. Further, under the terms of the agreement, DNR shall not have the right to terminate the LABS lease prior to September 30, 2004, nor shall any action by DNR result in a reduction of the rents payable under the lease unless DNR reimburses Morgan Islanders, Ltd. for any such reduction.

The Question

According to federal regulations that govern the NERR program, the DNR is required to develop a plan, which must be approved by NOAA, to guide future use and management of Morgan Island. However, before a management plan can be written, the DNR must decide whether to allow LABS to continue to lease Morgan Island for the purposes of maintaining a rhesus macaque breeding colony there after the current lease term expires in 2004. Therefore, the DNR Board requested staff to assess the following question:

"What are the positive and negative aspects of maintaining the rhesus colony on Morgan Island?"

Methods

DNR staff, led by the Marine Resources Division (MRD), were charged with performing an assessment of the question posed above. Representatives from MRD, the Executive Office, the Law Enforcement Division, and the Wildlife & Freshwater Fisheries Division, met several times to discuss the pros and cons of maintaining the lease to LABS. Additionally, staff queried representatives of the FDA on their views of the importance of the Morgan Island breeding colony, and attached to this report is a statement from FDA that describes that agency's interest in maintaining the rhesus monkey colony on Morgan Island (see attached).

What follows is a brief outline of staff's current assessment of the issues associated with maintaining the LABS lease beyond 2004. The outline lists both the positive and negative aspects of the issues based upon the staff's subject matter expertise. In contrast, the staff does not have the necessary qualifications or expertise to fully assess many of the human-health related aspects of the issues. For these issues, staff consulted with the SC Department of Health & Environmental Control for guidance (the DHEC statement is attached).

ISSUE ASSESSMENT

<u>Pro</u>

A. **Contribution to human health research:** The rhesus colony on Morgan Island was established in 1979 to provide a stable and secure source of animals for biomedical research. Since the establishment of the colony, animals from Morgan Island have been used in research on virology and immunology. Specifically, Morgan Island animals have been used in tests in an effort to develop vaccines for

AIDS and other human immuno-deficiency syndromes. FDA officials describe the Morgan Island colony as critical to the continuation of the global fight against AIDS and other global diseases. Finally, recent world events have focused renewed attention on bioterrorism threats, and FDA suggests that researchers are "waiting in the wings" to tap the animals for use in determining treatment regimes for pathogens such as anthrax and smallpox.

B. **Revenue generation ($787,500/year):** The lease between LABS and the agency will generate $787,500 per year in calendar year 2004. After the DNR's obligation to Morgan Islanders, Ltd. is fulfilled (with payment of the first $175,000 received in 2004), the agency stands to receive this sum annually for allowing LABS the privilege of using Morgan Island for a breeding colony. This source of revenue could be categorized as "program income" and used in any number of ways to enhance agency efforts in land protection, public access and recreation, education, and other conservation efforts. Land protection funds from the federal government often require matching non-federal funds, and in this time of rather austere budget circumstances, finding the requisite non-federal matching funds is no easy task. Depending upon matching requirements, lease receipts could be used to leverage significant funds for land acquisition and other grant-funded activities. These funds could potentially be used to provide public use and access elsewhere along the coast and throughout the state.

C. **Restricted public access equals low human impact to the island:** Although there has been no assessment of the environmental impact of monkeys nor of any potential impact of increased public use of Morgan Island, there is a general understanding among staff that increasing public use of Morgan Island could have a greater impact on the natural resources of the island. LABS operations on Morgan Island follow strict protocols to ensure the health and well-being of the animals and their caretakers. The colony is intensely managed (feeding, watering, health screenings, etc.) to minimize stress in the animals. To these ends, the animals are free ranging on the island, and their impact on the natural resources on and around the island appear minimal. Absent the lease to LABS and given the present and foreseeable financial climate, staff do not anticipate having the means to deploy staff to the island to oversee day-to-day public use and visitation to the island. As a result, there is the real potential that the condition of the island and its resources might suffer at the hands of unmanaged public access. Staff should place a priority on determining the actual impacts of both monkeys and humans on Morgan Island.

D. **Animal welfare:** Alternatives to monkey culture (cages/pens/cribs) appear to be less desirable to many interests, including animal culture experts, researchers, and animal rights interests. Morgan Island represents the last managed colony of free-ranging rhesus monkeys in the United States. If the DNR chooses to cancel the lease to LABS, the impacts to the supply of rhesus monkeys for biomedical research are unclear. In order to maintain adequate numbers of animals for research, LABS will likely continue to manage a colony of monkeys in captivity

using cages, pens, and corncribs. LABS staff have suggested that animal welfare interests, while opposed to the use of animals for medical research, believe that it is more appropriate to culture and maintain monkeys in a setting much like Morgan Island where captivity-induced stress is minimal if not non-existent. These groups are likely to be less concerned over animal welfare in a facility such as Morgan Island as some view it as a preferable alternative to confined management and culture of the animals.

E. **Research opportunities:** Staff are not aware of any extensive research that has been conducted on the impacts of large monkey breeding operations on natural resources. Staff are aware of one monkey breeding operation on two islands in the Florida Keys that has ceased operations due to the impacts of monkeys on both water quality and native vegetation. Charles River Laboratories' operations on Summerland Key and Key Lois came under scrutiny after it was disclosed that monkeys on those islands were destroying the threatened red mangrove and impacting the water quality around those two islands. After a protracted legal dispute, Charles River Labs agreed to cease its operations in the Florida Keys and eventually turn over their land holdings to the State of Florida and the U. S. Fish & Wildlife Service. The Morgan Island situation is different, however. Staff have found no evidence to suggest the animals are impacting any threatened or endangered plant or animal species, nor water quality. Continuation of the LABS lease and continued presence of the animals on Morgan Island would present a research opportunity unique in this country: an area with marginal human impacts where the effects of a large monkey breeding operation on the natural environment could be studied and documented.

Con

A. **Monkeys are a non-native species:** The State of South Carolina has developed a precautionary approach to the importation, possession, and release of non-native species in this state, although there are notable exceptions, such as in the case of the pet/aquarium trade. Rhesus macaques are not native to South Carolina. Given the mission of the DNR to conserve the natural resources of South Carolina, this precautionary approach suggests that any action by the DNR to facilitate the importation or possession of non-native species should be done only after the agency assesses the risks to native species and resources.

B. **Pathogens:** Like all organisms, the global rhesus macaque population carries certain pathogens (viruses, bacteria, parasites) that pose a threat to other organisms, including humans. Reflecting the distribution of pathogens in rhesus macaques worldwide, the animals on Morgan Island are known carriers of the Herpes-B virus. This virus, which is non-fatal in the monkeys, can be transmitted to humans. Although the number of documented cases of B-virus infection in humans is exceptionally low (~45 cases worldwide since 1932), human infection results in a 70% mortality rate. Epidemiologists manage risk of B-virus infection as an occupational concern for animal handlers; it is generally not viewed as a

threat to public health. While the risk of B-virus transmission to humans is exceptionally low, it remains a risk. Additionally, there are other pathogens that also pose a threat to humans. Reflecting the State's precautionary approach regarding non-native wildlife, Section 50-16-30 of the S. C. Code of Laws (1976) states "(i)t is unlawful for a person to possess, transport, or otherwise bring into the State or release or introduce into the State any diseased wildlife or other animal that reasonably might be expected to pose a public health or safety hazard as determined by the South Carolina Department of Health & Environmental Control after consultation by the department." The statute clearly identifies that disease-carrying non-native species are matter of significant concern.

C. **Risk/liability of public health threat:** Given the risk of pathogen transmission from monkeys to humans, prudent risk management dictates that one minimize the interaction of humans with infected animals. Therefore, continued presence of the animals on Morgan Island would preclude access to the island's high ground by the general public. Public ownership of Morgan Island by a natural resources agency carries with it the presumption to provide at least limited public access to the island, which would be at odds with the pathogen risk management strategy. Although the risk of B-virus transmission from a monkey to a citizen is exceptionally low, it is not non-existent. Staff believe the DNR should not risk a single infection of the public with B-virus from a Morgan Island animal. This position is based not upon potential legal liability, but rather upon important concerns over the DNR's relationship of trust with the public and personal reservations of many DNR staff. DNR Legal Counsel has advised that in typical landlord/tenant relationships, the landlord generally is not legally liable for any damages and harm suffered by a third party resulting from action of the tenant (e.g., infection of a member of the public by a Morgan Island animal). Even though this may be a sound legal principle that minimizes the legal and financial liability of the DNR for actions by LABS, staff are concerned that ANY infection of a member of the public from a Morgan Island monkey would result in tremendous political and public relations, if not legal and financial, liabilities for the agency.

D. **Restricted public access (at least to the main portion of the island):** Although there are notable exceptions such as the Yawkey Center and certain Heritage Preserves, the DNR's programs and efforts have traditionally been focused on enhancing public access to lands for recreation, not on restricting access. The public access imperative is paramount in an area such as the ACE Basin, where the combination of public and private efforts in landscape conservation have resulted in patchwork of areas with different degrees of public access. Additionally, the federal funds used to acquire Morgan Island obligate the DNR to develop a management plan for the land that carefully considers the need for public access.

E. **Unknown impacts to natural resources from monkey colony:** As mentioned as a possible "pro" above, the impacts from the monkey colony on key natural

resources such as vegetation, water quality, mammals, birds, and others remains to be determined. Although no baseline surveys of Morgan Island exist against which we can compare the present condition, the monkeys appear to have had minimal impact on the resources on and around Morgan Island. However, we cannot make a definitive statement to that effect. There is evidence of elevated fecal coliform in water quality sampling performed by the S. C. Department of Health and Environmental Control, but the source of this fecal matter has not been definitively documented. Given the state's preference for a precautionary approach, as embodied in the non-indigenous species law, staff recommend that an ecological characterization of the resources on and around Morgan Island be performed if external funding can be obtained to support it. Such a characterization would facilitate the development of a management plan for the island. This characterization should include an archaeological survey to determine the nature and extent of archaeological resources.

F. **Animal welfare:** The DNR has had some experience in the past few years dealing with animal rights interests. The animal rights interests are pushing a philosophy that is very different than one to which the DNR is accustomed, and any continuation of the lease to LABS could be painted by animal rights interests as supporting improper treatment of the animals. However, as noted in the "pros" section, removal of the animals from the island may result in their being placed in less desirable conditions.

G. **Security:** Presently the LABS operations on Morgan Island are basically daylight-only. That is, there is no regular after-hours presence or surveillance of the island. There have been several documented cases of trespassers on the island. Staff believe that public ownership of Morgan Island will only serve to heighten public interest in visiting the island, which could result in greater problems with trespassing and security. Staff believe that greater efforts should be made to enhance security of the island in order to minimize potential problems with trespassing, vandalism, and interaction between the public and the animals.

H. **Escapement of monkeys:** Since the monkeys were introduced to Morgan Island in 1979, stories and accounts of escaped monkeys in various portions of northern Beaufort County have become part of the local lore and intrigue associated with the LABS operations. However, LABS has documented only seven monkey escapes from the island as follows:

Year	Recapture location
1980	Sams Point
1981	Sams Point
1981	St. Helena
1982	Sams Point
1983	Royal Pines area of Ladys Island
1985	Coosaw Island
1996	Pine Island (across Morgan River)

It is notable that only one of the seven documented escapes has occurred in the past seventeen years. LABS personnel assert that this is so because the animals are well managed for and have no reason to leave an environment where they are cared for (LABS ensures that animals on Morgan Island are fed, watered, and healthy) and free to roam unencumbered and relatively unmolested. However, it should also be noted that since 1979 Morgan Island has experienced no significant hurricane activity. LABS does have a protocol in place for capturing escaped animals, and those animals that have escaped are never returned to Morgan Island. The risks associated with escapes from Morgan Island include the potential for pathogen transmission. Further, there is a colony of rhesus macaques that became established in the wild after they were imported to the Silver River drainage in central Florida for filming of the movie "Tarzan" in the 1930s. These animals have demonstrated a capability of establishing and maintaining a population of animals in the wild. Regardless of the outcome of the DNR Board deliberation on the future of the monkeys, staff recommend that LABS enhance their security protocols to ensure that monkeys do not escape from the island.

Other factors

As mentioned above, there are several other factors that must be weighed in deciding whether to continue the lease to LABS of Virginia.

A. **NOAA Interests:** According to the Code of Federal Regulations that governs the NERR program, NOAA must approve the management plan for the ACE Basin NERR. The Department acquired Morgan Island with the intention of including it within the ACE NERR. Before the ACE NERR Management Plan can be updated (and reviewed by NOAA), the decision must be made whether the monkey colony on Morgan Island will be allowed to continue or not. Upon determination by the DNR Board of the future of the Morgan Island monkey colony, DNR staff will update the ACE Basin NERR Management Plan to incorporate Morgan Island. After the plan has been developed, NOAA will review it for, among other things, suitability and consistency with the goals and objectives of the NERR program as a whole. NOAA staff have raised some concerns about the appropriateness of the monkey colony within the NERR, and NOAA has in the past opposed non-native species within specific NERR sites (horses in North Carolina's Rachael Carson NERR, for instance). Continuation of the lease to LABS might invite further scrutiny by NOAA.

B. **The Florida Experience:** The State of Florida has had a great deal of experience in dealing with rhesus monkey colonies. As mentioned above, the Silver River colony has ranged freely in central Florida for decades, and sources familiar with the Silver River colony report numerous problems associated with aggressive behavior of these animals towards visitors of nearby tourist attractions. Additionally, the Charles River Labs colonies were a source of great frustration for officials and citizens in the Florida Keys. These animals defoliated the islands, created water quality problems, and were consistently escaping their island for surrounding areas. Officials with the Florida Fish & Wildlife

Commission advised us that unless the monkeys are actively managed by highly trained and motivated handlers, they would require constant attention from DNR officials. It is important to note, however, that there have been no known cases of Herpes-B infections of citizens by animals of either of these colonies.

C. **Adequacy of Lease Payments:** Continuation of the LABS lease and providing public access to the area under the lease are mutually exclusive. Therefore, the Board much consider whether conservation and recreation interests are being adequately compensated for the loss of these values. The lease payment of $787,500 provides a return on a $20 million investment (the reported purchase price) of about 4%. Given that the prime rate is currently 4-3/4%, the lease is under-valued. It is certainly not enough to recover the lost values elsewhere, assuming they are available. A full review of federal-aid regulations might even reveal that the lease payments are not only inadequate, but that full market-value lease compensation is due to the federal government, rather than the DNR.

Summary

The question of what to do regarding the lease of Morgan Island to LABS is a very difficult one. On the one hand the opportunity to support the nation's biomedical research enterprise and security is a significant means by which the DNR can contribute to the "greater good" of society. However, the need to segregate the monkeys from the public precludes supporting both the public access and biomedical research imperatives; the risks of disease transmission and/or injury to both the monkeys and the public is too great to allow any substantial public/monkey interaction.

The decision on whether to continue the LABS lease hinges on the degree to which the DNR is comfortable with the idea that the risks associated with the monkey colony can be managed and that restricting public use of the high land is appropriate and is in the over all public interest.

The Benefits of Continuing the Rhesus Monkey Breeding Colony on Morgan Island

Statement of the U. S. Food and Drug Administration
23 July 2002

Morgan Island is a unique environment in which to house one of the more valuable resources that the United States Government has for biomedical research, a rhesus monkey breeding colony. This breeding colony has supported a number of public health initiatives over the 23 years of its existence. It has been critical in providing animals to ensure the safety of polio vaccine and to study the course of disease and potential prevention of the HIV virus. In addition to continuing to support these projects, the offspring of Morgan Island animals will be needed in a number of new research initiatives, some involving counter terrorism agents such as anthrax vaccine. As a result of their usefulness as a model for HIV and other infectious diseases, rhesus monkeys are in high demand and their supply has become more limited for biomedical research. As explained below, moving the colony off of Morgan Island would exacerbate the current shortage of rhesus monkeys.

This resource as it stands now is irreplaceable and not reproducible in any other location for reasons that will follow. The project began in 1979 when the US Food and Drug Administration (FDA) established the breeding colony on Morgan Island for the purpose of providing one-year-old monkeys needed for the safety testing of polio vaccine, a vaccine received by nearly every child in the US. At that time, the FDA had 3 other rhesus monkey breeding facilities, which also supported the polio vaccine safety-testing program. In ensuing years, technological improvements in the production and testing of polio vaccine reduced the need for monkeys. Because the Morgan Island facility was the most natural environment for the animals, as opposed to the corn crib or corral systems used in most breeding facilities, and because it is the most economically efficient way to provide care for the animals, it was continued as the only breeding colony, and the FDA divested themselves of the other 3 colonies. Then, in the late 1990's, the demand for monkeys rose rapidly as a result of their usefulness as a model for HIV infections in humans as well as a model for a number of other pre-existing and emerging infectious diseases in humans. Recent homeland security issues, Department of Defense initiatives to improve anthrax vaccines and therapies, and the need to stockpile polio vaccine have put added pressure immediately on the need for rhesus monkeys. Moving the breeding colony from Morgan Island will significantly reduce the number of animals available for these projects for the indefinite future for the following reasons:

--It will take a minimum of one year to trap as many monkeys as we can on the island. During that time, the normal reproductive contact and frequency of contact between breeder males and females will be interrupted. Social groups as they currently exist on the island will be broken up and breeding animals will be exposed to the stress of a new, less natural environment. All of these factors will reduce the ability of mature females to become pregnant. Our data from when we moved the colony onto Morgan Island in 1979

showed that, even in this natural environment, it took 5 years before the colony returned to its production rate prior to the move.

--The production rate historically in this colony has been 75% of females producing a live birth each year. This is considered an excellent number, and is mainly due to the free-ranging nature of the environment. Our experience with the more restricted corn crib and corral systems that trapped adults would be moved to is that they have a production rate of 5 to 10% less, resulting in further reduction in productivity even after a 5 to 10 year recovery period.

--Our expectation is that under the best circumstances, even after a year of intensive trapping, the best that we could hope for is trapping 80% of the animals on Morgan Island. Trapping this percentage will require much more aggressive efforts than those that we currently use. This means that about 600 animals, mainly prime breeding age animals, will remain on the island at the end of the contract in spite of our best efforts. Not having these breeding animals in a relocated colony will add the to reduction in production that no amount of time will replace

To summarize, moving the colony will significantly reduce the number of offspring produced per year. This drop in production will further exacerbate the current shortage of animals available for research projects that are critical preventing and treating a number of infectious diseases as described below. The FDA believes there are many benefits to the monkeys, to the public health, and to the management of the breeding colony itself in continuing the breeding colony on Morgan Island. These benefits are summarized as follows:

Benefits For The Public Health

--Morgan Island has supplied animals for the safety testing of childhood vaccines, most significantly for polio vaccine safety testing. The safety of all childhood vaccines is especially important since the recipient population is young and healthy so that any adverse events resulting from their administration must be minimized. These monkeys have played a critical role in assuring adequate and safe immunization of all citizens. Additionally, the seed strains of virus for the childhood vaccines for measles, mumps and rubella are also tested in rhesus monkeys as well as any proposed new vaccines which may inadvertently effect the central nervous system. It should be noted that all animal use takes place in biomedical research facilities and not on the island.

--These monkeys are used for vaccine development for childhood Paramyxovirus infections. These viruses account for 40% of all hospitalizations of children for respiratory disease.

--The rhesus monkey is the preferred model for vaccine and therapy development and testing for AIDS research. This colony is the main source of animals for intramural AIDS research projects within the National Institute of Allergy and Infectious Diseases (NIAID). Several hundred more rhesus monkeys per year could be used by other NIH researchers if they were available.

--These monkeys are used in Dengue Fever vaccine development studies. This mosquito-borne viral disease, which causes a hemorrhagic fever, has been diagnosed in the US and cause millions of cases world-wide. Currently, there is no vaccine.

--These monkeys are used in malaria research. Over 2 million people worldwide die each year of malarial infections and hundreds of millions of people are infected. It is widely distributed in Africa, Asia, and Latin America. No vaccine exists.

--These monkeys are used in research projects against Hepatitis E infections, a viral disease related to transfusion hepatitis viruses and food-borne hepatitis virus. Viral hepatitis infects more than 500,000 Americans, resulting in the death of 16,000 from complications of the infections. There is no vaccine for hepatitis E virus.

--These monkeys are used for leishmania vaccine research. This protozoal disease is endemic in South and Central America. It can cause death in 5-10 % of the cases or cause disfiguring skin lesions. There is no vaccine.

--West Nile Virus causes an emerging disease in the United States that was introduced here in 1999. It appears to be spreading out from its toehold of introduction in the New York City area. At the end of 2001, 149 human cases had been reported including 18 deaths, usually due to its attack on the brain in severe cases. Rhesus macaques are a useful model for this disease.

--Waiting in the wings are collaborators in the Department of Defense who need rhesus monkeys to improve the vaccine and to examine alternative immunization techniques against anthrax infections. Rhesus monkeys will also be useful in evaluating and determining the safety of new therapies against this bacterium.

Benefits For The Animals

--Morgan Island is the most natural environment for housing rhesus macaques. Because of the space provided by the 400+ acre island, the monkeys are allowed to form their own social groups and have adequate space to separate one troop from another. This reduces aggressive behavior, which is a problem in all of the more confined systems of housing. If the colony was to be moved from the island, the animals would be housed in either corn cribs or small corrals on the mainland where the close confinement and lack of visual barriers to other animals increases the potential for conflict between animals, resulting in increased numbers of fighting wounds.

--It should be noted that, other than behavioral observations conducted by NIH investigators (which would end after 12 years of study should the colony be moved), no research of any kind takes place on the island. As a matter of fact, the animals are handled only 4 times a year when technicians trap approximately 20 % of the colony for the purpose of TB testing, tattooing, and other health monitoring.

Other Issues

--In the 23 years of operation, there have been no cases of serious diseases transmitted from monkeys to the animal care staff or to anyone in the surrounding community. Although the Herpes B virus is present in the colony, at least 90% of all one year old and younger monkeys are free of the virus (40 % of the colony). Human cases of infection with the herpes B virus are extremely rare, even among individuals who handle monkeys regularly. Since 1933, only 46 cases have been reported in the literature. No transmission of herpes B from the Morgan Island monkeys to handlers or the nearby community has ever been reported.

--Only 7 monkeys have ever escaped from the island since the colony began 23 years ago and all but one of these escaped in the first 5 years of the project. No monkey has escaped in the last 7 years. Based on animal behavior models and our observations of the colony over the past seven years, it appears that this decline is due, in part, to an aging and settling in of the population, and the natural selection against those animals that have attempted to swim to the mainland.

--The island and its facilities are all fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). This status is considered the gold standard for laboratory animal housing and reflects the highest standards of animal care as determined by an independent evaluation. It assures the public that animal care on the island is excellent.

--It should be noted that if animals had to be removed from the island, we have estimated that a maximum of 80% of the colony will allow themselves to be trapped. As many as 600 monkeys could allude capture and alternative measures may be needed to be considered to clear the island of remaining monkeys.

In summary, the Morgan Island breeding operation has functioned for 23 years without any major or even minor incidents of damage to the surrounding community or to individuals. The benefits to progress in biomedical research, especially in the area of prevention of infectious diseases, are significant. Considering the current shortage of rhesus monkeys for disease prevention research, removing the breeding colony from Morgan Island will have serious repercussions on the ability of NIH and FDA to support such research programs. The loss to production of moving the colony will take years to decades to recover. It is our opinion that a risk-benefit analysis comes down strongly in favor of the benefits to the public health of continuing the rhesus monkey breeding colony on Morgan Island.

REPORT TO EXECUTIVE BOARD OF SOUTH CAROLINA DEPARTMENT OF NATURAL RESOURCES:
RISKS TO INHABITANTS OF BEAUFORT COUNTY FROM THE PRESENCE OF RHESUS MONKEYS ON MORGAN ISLAND
James J. Gibson. MD, MPH, South Carolina State Epidemiologist

About 2500 non-human-primates (NHP), Rhesus monkeys, live free on Morgan Island today. This primate colony began in 1979 with the introduction of wild Rhesus monkeys by federal government health agencies to begin a breeding colony to supply medical research needs, primarily research on development of human vaccines against such diseases as polio, hepatitis B and HIV. LABS Inc of Virginia manages this primate breeding process on the Island and at nearby sites in Yemassee and Hampton.

The Rhesus monkeys on Morgan Island are not fenced in or restricted from leaving the island but in fact escaped monkeys are rarely found on the neighboring St Helena island. Although it is likely that not every escape is detected, we can be relatively confident that escapes are uncommon because there is an effective system to detect escapes and recapture the animals, which has recorded less than one escape per year in recent years. The lack of escapes is attributed to the facts that such monkeys are strongly social animals who do not like to leave their social groups, and are fed regularly on the island.

These facts are important because the only way that the local human population could become ill because of these NHP is through actual contact with an escaped animal resulting in an injury (e.g., a bite) or in direct contact with the animal or its fresh secretions. The only exception to this statement is possible contact with tuberculosis (TB), which is airborne but is usually transmitted indoors to close, regular family contacts and also is almost non-existent in animals on the Island owing to LABS' careful TB control program.

The possibility of the transmission of viral, bacterial or parasitic diseases through such contact must be considered because such primates can be infected with a variety of infectious agents which are potentially transmissible to humans. I will review briefly the likelihood of such transmission of these infections from an escaped Rhesus monkey.

There are several categories of infectious agents that infect Rhesus monkeys and that could be transmitted from Rhesus monkeys to humans. Considering only the agents that might conceivably be present in the Morgan Island colony, these include:

Viruses: Hepatitis A and B, simian Herpes B virus, rabies virus, and conceivably several vaccine-preventable diseases (polio, Rubella, measles, chicken pox)

Bacteria: Salmonella, Shigella, Campylobacter, Yersinia, possibly E. coli O157:H7, tuberculosis (TB),

Protozoa: Giardia, Cryptosporidium,

Of these diseases, there are several that cause illnesses that humans do not routinely encounter from exposures in their daily life (i.e. diseases for which monkey contact would increase disease risk for humans above that routinely encountered by them). These are: simian herpes B virus, hepatitis A and B viruses, rabies virus, the vaccine-preventable disease viruses (VPDs), and TB. However, careful screening for TB has shown clearly that it is not present in this colony. Hepatitis A and B, rabies and the VPDs are not natural NHP infections, have never been found in monkeys on the Island since 1979, and are therefore extremely unlikely to be present there. Thus of the above list, the only infection that is present in these NHP and offers a threat of serious disease to humans is simian Herpes B virus.

Simian Herpes B infection is a mild disease in Rhesus monkeys rather like most oral or genital Herpes cases in humans, causing recurrent slightly painful lesions in the mouth or genital area without apparent systemic symptoms. However, in the rare human infections it usually causes life-threatening and fatal skin lesions, systemic disease and encephalitis or meningitis. It does not cause asymptomatic human infections. Recent data suggests that several antiviral drugs (acyclovir, gancyclovir or valcyclovir) are quite effective in treatment if initiated soon after symptoms appear, and may be effective if given preventively.

While transmission of simian herpes B virus from NHP to humans has happened, there is substantial reason to think that such transmission does not happen at all easily. We know that humans and Rhesus monkeys have lived in close proximity in India and Africa for millennia, and contact with these monkeys has never been considered by those societies to be dangerous. Such monkeys live in heavily populated areas, have often been kept as pets and in some societies are worshipped as holy animals. In the medical literature from Europe and the US, there are about 45 cases of simian Herpes B in humans reported since it first was identified in 1932, almost all in persons whose occupation was handling and caring for monkeys. Considering that there has been occupational exposure of many thousands of individuals to captive monkeys since then, it is clear that the risk of getting this virus from monkey contract must be very small even for persons who handle monkeys daily (Mandell et al, Principles and Practice of Infectious Diseases, Churchill, Livingstone, 2002). It should be noted however that transmission of this virus from a bite of a NHP depends on the presence of Herpes B lesions on the monkey at the time of the bite, and it is known that stress in monkeys increases probability of appearance of lesions (see below).

How would we detect and measure the presence of a low-level risk of transmission specifically from the Rhesus monkeys on Morgan Island? A standard epidemiologic method of estimating risks from environmental exposures is to measure the risk in persons exposed to that factor occupationally, since they would be expected to have a more intense exposure than casually exposed persons in a community. Thus, we could look at the highest-risk group here, the monkey handlers on the Island, estimate their risk,

and conclude that the risk to anyone else would be lower than theirs. Therefore, on August 8, a DHEC Medical Director visited the LABS facility and examined the personnel records for almost all the LABS employees who had worked on Morgan Island since the colony began in 1979 (a total of 17 persons), and in addition examined a sample of 14 employee records from their Yemassee facility. The records of approximately one-third of the current employees were examined. Findings included the following:

- The Acting Director, Health and Safety Officer, Veterinarian (Animal Health Officer), current Employee Medical Officer and the prior Employee Medical Officer (now retired) all specifically denied remembering any deaths, unusual neurological disease, unexplained severe febrile illness, prolonged gastroenteritis, unusual rashes or lesions, Hepatitis A or B, Herpes B disease or tuberculosis in employees past or present.
- LABS' standard Policies and Procedures for employee protection from bites and infection, and for prevention of disease and diagnosis in the event of a bite from a NHP, were judged by both the DHEC medical officer and me to be effective. However, these have been in effect only since 1988 at the earliest. There are certain other policies and procedures that are needed in our opinion (see below).
- LABS Policies and Procedures for capturing escaped NHP appear effective and reasonable, but detecting escapes depends on the Morgan Island staff noticing when a specific monkey is missing, or a report from a resident of the local sea islands of the presence of a monkey.
- Fifteen of the 31 charts (almost half) indicated at least one exposure to NHP body fluids, including bites, scratches, needle sticks and splashed on mucous membranes. Seven were in employees of the Morgan Island facility. These were followed up as per protocol. No cases of Herpes B resulted.
- No cases of any syndrome resembling Herpes B, or of a febrile illness with neurological or skin disease, or gastroenteritis or TB were seen on the charts. Three employees converted their TB skin tests to positive fairly early in their employment, but there was no evidence in any of these that they had gotten infection from monkey exposure.

In addition it should be noted that Beaufort County follows up all case reports of tuberculosis and hepatitis B, and none of these have been attributed to employment at LABS facilities.

Conclusion: The main serious potential human health outcome from the Rhesus monkeys on Morgan Island appears to be human Herpes B infection. The likelihood of this happening in any year appears to be extremely low, perhaps in the range of the risk of being struck fatally by lightning, or lower. This is because of the rarity of monkey contact to citizens of Beaufort County, and the low probability of infection when a bite contact happens. We can however think of situations in which both these probabilities might be somewhat increased, for example if a major hurricane struck the Beaufort area and some monkeys left the island (most would probably remain in the tops of trees on the island). We are also somewhat concerned about the possibility of a new infectious disease being introduced to the monkey colony unintentionally or intentionally. We make some recommendations about these below.

However, while a full discussion of the benefits to the citizens of South Carolina of this breeding colony is not in the scope of this report, it is important that this should be considered also. NHPs are essential to the development of certain vaccines, in particular vaccines against the Human Immunodeficiency Virus which is now epidemic in South Carolina, and in many areas of the United States and the world. There are only a few sites in the US which produce laboratory monkeys for such work. The benefit of developing such vaccines should be weighed against the potential risks of the presence of this colony.

Recommendations:

a) The risks to human health in Beaufort County from the presence of Rhesus monkeys on Morgan Island are quite limited, but there exists an extremely low-level risk of a case of Herpes B encephalitis occurring. This risk will be strongly influenced by the behavior of the inhabitants of the surrounding area in avoiding contact with escaped monkeys from the colony, and in not violating the law by trespassing on the island. A planned public communication campaign could both reduce this risk, and reduce irrational fears of imagined dangers from the monkeys.
b) LABS in coordination with DNR should write a plan that projects the likely situation if a major hurricane should strike the Beaufort area, and how to deal with it.
c) LABS should write a standard procedure for surveillance for an unexpected epidemic of illness or death in the colony on Morgan Island and for diagnosing and dealing with it.

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Al Seegars, DVM, SC Department of Natural Resources
Mary Helen Niemeyer, MD, MPH, DHEC